PART I

ANTI HISTAMINE, ANTI-INFLAMMATORY, ANTI MICROBIAL ACTIVITY OF

"*AIVAELI SAMOOLA CHOORANAM*"

(*Diplocyclos palmatus (L)C.Jeffrey*)

&

PART II

"*NAVACHARA CHUNNAM*" FOR ITS NATURALLY CURING

POLYCYSTIC OVARIAN SYNDROME

The dissertation Submitted by

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Under the Guidance of

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PART- II

1. INTRODUCTION

Siddha system of medicine is an endowment of healing system granted by Siddhars for making the people with complete physical and mental health. Siddha is grounded on 96 fundamental principles, based on which the physiology of humans, pathology and diagnostic methodology of diseases, pharmacological action of medicines and astute treatment of diseases are explained.

Need for preservation of medicines, the need for long half life for medicine, the need for coping up the different forms of disease in various conditions paved the way for rise of 32 different forms of internal medicines and 32 different forms of external medicines in Siddha. In the field of pharmacology, three kinds of natural sources are utilized for medicine purposes which include herbs, metal &minerals and animal sources.

The application of drugs, indicated for different group of diseases are based on the taste of the drug which, in turn, based on *Panchabootham*. *Siddha* classifies diseases into 4448. All these diseases can be grouped under three humours- *Vatham,Pittam,Kabam*. These three, in turn, get their basics from *Panchabootham*. In common, *Panchabootham* are the key handled by the *siddhars* to diagnose the disease and proper apt selection of medicine for the disease.

Herbal sources are given prior importance in *Siddha* among the other natural sources, as their availability, purification process, medicine preparation process are comparatively handful and easier. Herbs have a traditional history of use, with strong roles in cultural heritage, and in the appreciation of food and its links to health. Moreover, Plants have the ability to synthesize a wide variety of chemical compounds that are used to perform important biological functions, and to defend against attack from predators such as insects, fungi and herbivorous mammals.

Phytomedicine or Herbal medicine, is the science, art and discovery of using botanical remedies to treat illness. The term Phytotherapy describes the therapeutic application of plants. This term was coined by the French physician Henri leclerc(1870-1955) who published numerous essays on the use of medicinal plants.(Benor DJ). Many of these phytochemicals have beneficial effects on long-term health when consumed by humans, and can be used to effectively treat human diseases. At least 12,000 such compounds have been isolated so far; a number estimated to be less than 10% of the total. (Cobiac L, *et al)*

Aivaeli(Diplocyclos palmatus) is such a kind of medicinal value rich herb, indicated for oligospermia, female infertility, edema, worm infestation, ECZEMA and arthritic pain in *'Pathaartha guna vilakkam'*-an important gallery of Siddha medicines.

Skin care is the lacuna in modern medical field where herbal medicines are slowly making the footprint and trying to establish its therapeutic values in recent days. In that sake *Aivaeli(Diplocyclos palmatus)* can contribute its role as it is indicated for eczema in Siddha literature.

Skin is the organ of beauty and protection. Eczema is one of the skin ailments which affect this beauty and protective function of skin. Thus it affects physically and mentally. Diseases of the skin account for a great deal of misery, suffering, inability and economic loss. Besides this, they are a great handicap in the society, because they are visible.

The word 'Eczema' seems to have originated in AD 543 and is derived from the Greek word '*ekzein*' meaning 'to boil out' or 'to effervesce' (Andrews). Baer describes "Eczema" as a pruritic papulovesicular process which in its acute phase is associated with erythema and edema and which in its more chronic phases, while retaining some of its papulovesicular features, is dominated by thickening, lichenification and scaling.

Assessment of epidemiological data in the UK has also found an inexorable rise in the prevalence of eczema over time. (Gupta R, *et al,* 2004). The incidence and lifetime prevalence of eczema in England have also been reported, such that an estimated 5,773,700 or about one in every nine people have been diagnosed with the disease by a clinician at some point in their lives. (Simpson CR, *et al* March 2009).

Finding anti-histamine, anti-inflammatory and anti-microbial activity of *Aivaeli(Diplocyclos palmatus)* will add a feather on cap of its pharmacological activities. This study is not yet done before. Hence, to add a medicine of choice for eczema and to add a pharmacological support for *Diplocyclos palmatus*, detection of anti-histamine, anti-inflammatory, anti-microbial activity of *Diplocyclos palmatus* will stand worthwhile.

The author decided to evaluate anti-histamine, anti-inflammatory and anti-microbial activity of *Aivaeli(Diplocyclos palmatus) samoola chooranam.*

2. AIM AND OBJECTIVES

AIM:

The principle aim of this study is evaluate the efficacy of the drug *Aivaeli samoola chooranam* in the management of KARAPPAN (Eczema) in pre-clinical and clinical aspects. Eczema is relapsing or persistent pruritic disorders that affect on the quality of life.

OBJECTIVES:

The most important objectives of the study are

- To study the pharmacognostic features of the plant *Aivaeli (Diplocyclos palmatus)* this includes correct taxonomic identification of the plant with macro and microscopically details.
- To have a collective review of the literature.
- To prepare the drug according to *Siddha* classical text.
- To subject the drug to physico-chemical standardization.
- To identify the phytochemical constituents of the drug.
- To subject the trial drug to chemical analysis.
- To study the acute toxicity of *Aivaeli samoola Chooranam* according to OECD guidelines.
- To determine the pharmacological activity (Anti histamine, Anti inflammatory, Anti microbial activity) of *Aivaeli samoola chooranam*.
- To assess the therapeutic potential of the drug through clinical trial for the management of *Karappan*

3. REVIEW OF LITERATURE

3.1. BOTANICAL ASPECT OF THE PLANT:

Botanical name: ***Diplocyclos palmatus(L) Jeffrey***

Synonyms:

Bryonia palmate L

Bryonia laciniosa L.

Family: *Cucurbitaceae* (T.Pullaiah 2006)

The name *Bryonia* meaning 'to sprout' in Greek, refers to vigorous growth of herbaceous stems that are produced annually from large perennial roots. (Kirtikar *et al* 1987)

SCIENTIFIC CLASSIFICATION

Kingdom-Plantae

Phylum-Magnoliophyta

Class-Angiospermae

Order-Cucurbitales

Family-Cucurbitaceae

Genus-Diplocyclos

Species-palmatus

Vernacular Names

Tamil : *Aivaeli, Aivirali, Sivalingakkay, Aiviralkkovai,*

English : Lollipop climber, striped cucumber, native bryony

Sanskrit : *Liagini*

Hindhi : *Sivalingi*

Kan : *Lingatondi*

Mal : *Neyyunni, Sivalingakkaya, Neyyurwni, Aiviralikkova, Sivavalli*

Tel : *Lingadonda*

Description:

Chromosome number 2n=24

Perennial, monoecious herb climbing by bifid tendrils. Stem up to 6m long. Young stems spotted with darker green. Leaves alternate, simple; stipules absent; Petiole 2-10cm long; blade broadlyovate, palmately 5-7 lobed up to 14cm x 15cm;base cordate; lobes narrowly elliptical, margin sinuatedentate.

Inflorescence an axillary cluster, with usually both male and female flowers in same axil. Flowers unisexual,regular,5-merous corolla white to greenish-yellow; male flowers pedicellate with 3 free stamens; Female flowers subsessile with inferior one celled ovary, stigma 3-lobed.Fruit a subglobose, indehiscent berry 1.5-12.5 cm in diameter, solitary or clustered, red with silvery white longitudinal stripes(Grubben 2004)

Flowers & Fruits; April to December (T.Pullaiah *et al* 1998)

Ecology

Diplocyclos palmatus occurs in different types of vegetation, but usually in wet localities, e.g swampy forest, flood-plains and valleys at altitudes up to 1800 m. (Grubben 2004)

DISTRIBUTION

World-Tropical Africa, Indo-China, Malaysia, Southern China, Philippines and Australia.

India-In hedges and bushes all over India.(T.Pullaiah 2006)

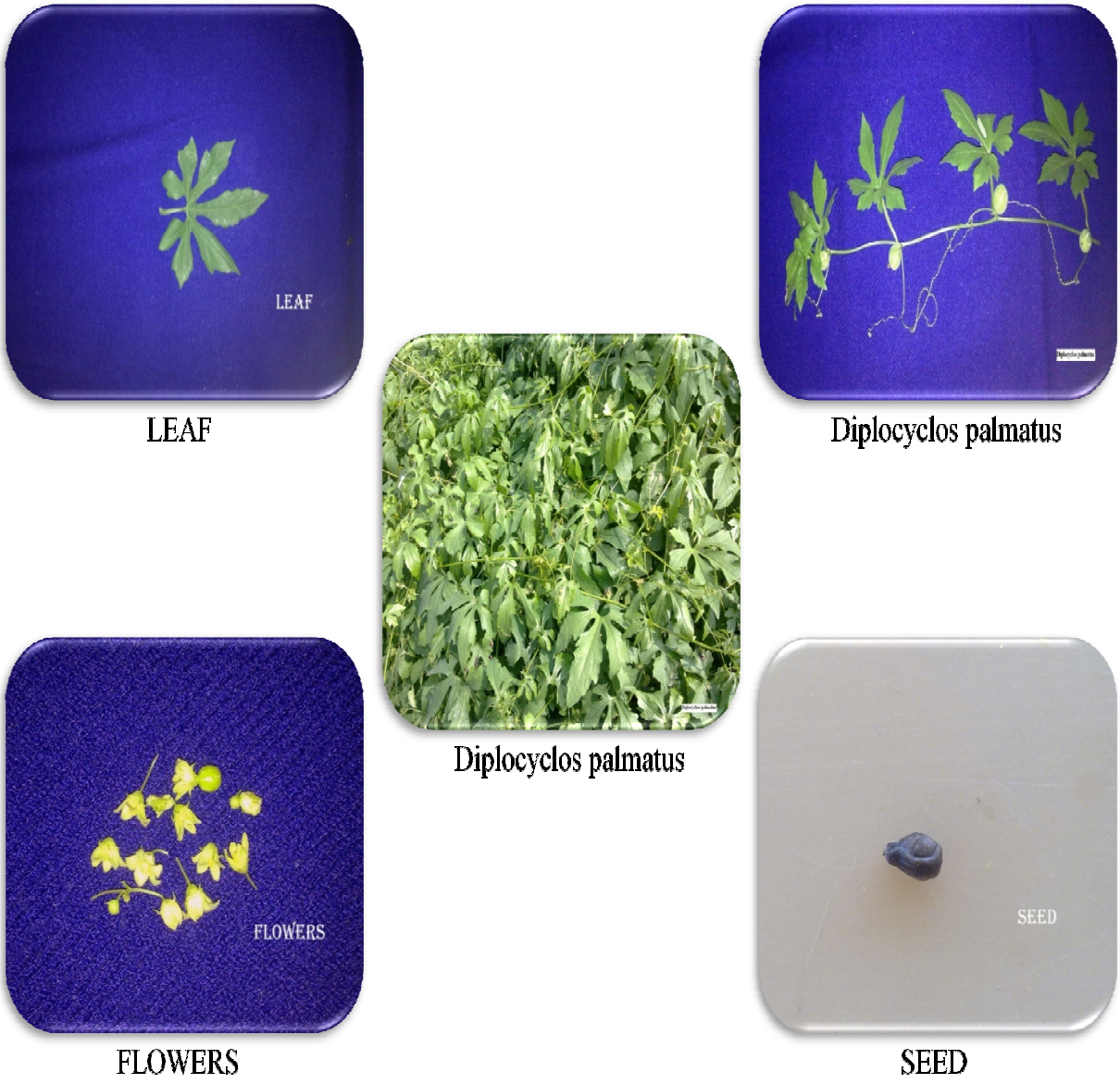


Fig. No.3.A **Diplocyclos palmatus**

3.2. SIDDHA ASPECT OF THE PLANT:

It is a climber with leaves looking like palm with five fingers and there are mild hairy growths found in both the surfaces of leaf. Seed resembles "*lingam*"shape.

Other names: *Aivirali*, *Aiviral kovai, Linga kovai*

Taste : Bitter

Action : Hot

Classification : Pungent.

Action : Laxative

Useful part : Whole plant (*Gunapadam mooligai vaguppu*)

பொது குணம்

விந்திளைப்புப் பெண்மலடு வீக்கம் மகக்கிருமி
சந்து வலிப்புண்ணும் சார்கரப்பான்- வந்துடலில்
ஏக்கமுறச் செய்யும் ஏந்திழையே ஐவேலி
போக்கிவிடு மென்றே புகல்

(பதார்த்த குண விளக்கம்)

Character:

Aivaeli can be used to treat Oligospermia, female infertility, oedema,intestinal worms, scabies, **eczema**, *megavayu* and cramps.

Method of collection:

At the time of fruit ripening, the whole plant of *Aivaeli* can be collected, dried in a sun shadow, powdered and can be used as medicine.

Dose:

1 to 2 *viragan (*4.2g to 8.4g) of the powder can be made into decoction or

¼ to ½ *viragan* (1g to 2 g) of the powder can be given with sugar.

If the powder is taken in excess quantity, It will act as Laxative.

So depending on body condition, the dose of *Aivaeli* powder should be chosen

சேரும் மருந்துகள்:

வங்க சுத்தி

சிவமுறையா மன்னை தினமுமற வாமற்

சிவமுறையா மன்னை தொடி சேரச்- சிவமுறையா

மாசகல மேதினியாய் வங்கமது தங்கமென

மாசகல மேதினியாய் வாய்

பொருள்-ஒரு பலம் வங்கப் பொடிக்கு, ஆறு பலம் ஐவேலி சமூலச்சாறுவிட்டு ஒரு நாள் முழுவதும் வெயிலில் வைத்து, மறுநாளும் அதுபோலவே செய்து, இவ்வாறு பத்து நாள் வரைக்கும் செய்து,இரண்டு நாள் சாறு விடாது உலர்த்தி,மறுபடியும் முன்போலவே செய்து,பிறகு ஒரு பானைக்குள் மேற்படி வங்கத்தை இட்டு,அதில் ஒரு படி ஐவேலி சாறு ஒரு மரக்கால் விட்டு, வாய்பொருத்தமுள்ள பாண்டத்தால் மூடிச்சீலை செய்து, பூமியில் குழி தோண்டி அதற்குள்ளிட்டு,சாம்பல் எருவால் மூடி, இருபது நாள் கழிந்த பிறகு எடுக்க பூமியின்று எழும் ஆவியால் வங்கம் ஒருவிதச் சிறந்த குணத்தை அடைந்து மாத்திரை முதலியன செய்தற்கும்,வாத வேதைக்கும் ஆகும். (தேரையர் யகம வெண்பா)

- அட்டகுன்ம சதுர்முக சூரணம்

தேத்தாவின் வேர்த்தோலும் ஐவிரலி வித்தும்

சிறுநாக விரையுடனே அருக்கன்வேர்ப்பட்டை

ஏத்தியே சமபாகந் தூளாய்ச் செய்து

இருநேரம் தேனில்வெரு கடியும் உண்ண

பத்தியுடன் மண்டலத்தில் அட்டகுன்மம்

பறந்துவிடும் இம்மருந்தின் ஆண்மைகண்டு

சுத்தமதாய்ப் பொசிப்புமிக உண்ணச்செய்து

சுகமளிக்கும் பத்தியங்கள் பிடிக்கத்தானே

பொருள்-தேற்றான் வேர்த்தோல்,ஐவிரலி விதை,சிறுநாக விதை,எருக்கன் வேர்ப்பட்டை இவை நான்கும் சமமாக எடுத்து தூள் செய்துதேனில் கலந்து இரண்டு நேரம் வெருகடி அளவு உட்கொள்ள நாற்பத்தெட்டு நாட்களில் அட்ட குன்மங்களும் பறந்துவிடும். (இராமதேவர் என்னும் யகோப்பு வைத்திய சிந்தாமணி)

❖ லிங்க மெழுகு

வைத்துமே ஐவிரலி பழுபாகல் சாறும்
வகைவகைக்கு ஒருசாமம் சுருக்குபோடு
ஆயத்துமே அரப்பொடியை பழச்சாறு விட்டு
அரைத்தந்த லிங்கத்தின் மேலே பூசி
உய்த்துமே பேய்க்குமட்டிக் காய்க்குள் வைத்து
ஒருபுடந்தான் போட்டெடுக்க முழுக்கட்டாச்சு
தைத்துமே சன்னிசுர தோஷ மெல்லாம்
சன்னுமே தொண்ணூற்று ஆறு வாதம்
செய்ததுமே மெழுகுசெய்ய வேணு மென்றால்
செவ்வகத்திப் பூப்பட்டை இடித்துச் சாறு
பயித்துமே பன்றியுட நெய்யுங் கூட்டி
பாங்காக சுருக்கிடவே மெழுகாகும் மே

பொருள்-இலிங்கத்திற்கு ஐவிரலிச் சாற்றில் ஒரு சாமம்,பழுபாகல் சாற்றில் ஒரு சாமம் சுருக்குக் கொடுத்து அயப்பொடியை எலுமிச்சம் பழச்சாற்றில் அரைத்து இலிங்கத்தின் மேல் பூசி, அதனை பேய்க்குமட்டிக் காய்க்குள் வைத்து ஒரு புடமிட்டு எடுக்க முழுமையான கட்டாகும்.சன்னி,சுரதோசம்,வாதம் தொண்ணுற்றாறும் போகும்.மெழுகு செய்ய வேண்டுமெனில் பூப்பட்டை இடித்த சாற்றில் பன்றி நெய் கூட்டி சுருக்கு கொடுக்க மெழுகாகும்.(பிரம்மமுனி வைத்திய சூத்திரம்)

3.3. MODERN ASPECT OF THE DRUG

Chemical constituents of the plant

Galactose specific lectin activity was detected in the mucilaginous coat surrounding the seeds of *Diplocyclos palmatus*. The lectin is a single polypeptide chain containing 2% carbohydrate. Punicic acid, a trans fatty acid that is rare in plants was isolated from *Diplocyclos palmatus* (G.J.H Grubben 2004)

Glucomannan: Extraction of defatted and decolorized seeds of *Bryonia lacinosa* with 1% aqueous acetic acid yielded a polysaccharide material, having D-glucose and D-mannose in the molar ratio of 1.00:1.01. Hydrolysis of the fully methylated seed gum furnished 2,3,4,6-tetra-O-methyl-D-glucose and 2,3-di-O-methyl-D-mannose in equimolar ratio. Partial hydrolysis of the polysaccharide furnished three oligosaccharides namely;

epigentiobiose, mannobiose, and mannotriose along with the component monosaccharides.(Vandana Singh *et al*, 2006)

Goniothalamin: Goniothalamin, a natural occurring styryl-lactone is a novel compound present in the whole plant of *Bryonia lacinosa* with putative anticancer activities. (Wen-Ying Chen *et al,*2005)

They extracted the whole plant powder (750 g) with methanol in a Soxhlet apparatus. The MeOH extract was subjected to fractionation with petroleum ether (50 ml), chloroform (50 ml) and ethyl acetate (40 ml) successively. From the ethyl acetate fraction goniothalamin (58 mg) was isolated by washing with diethyl ether followed by recrystallization. (Ashik Mosaddik M *et al,* 2000)

Arabinoglucomannan: It is a polysaccharide material, having d-glucose, d-mannose and l-arabinose in the molar ratio of. 5.00:3.01:4.00. It is yielded from the extraction of the pulp of ripe berries of *Bryonia lacinosa* with 1% aqueous acetic acid. (Singh *et al 2009*) evaluated the polysaccharide Arabinoglucomannan for the microbial activity and was found to be active against Escherichia coli with a minimum dose of 6.25 mg/mL (Singh *et al,* 2009)

The plant contains one of the Bitter principle, known as ***Bryonin*** (Dr.K.M. Nadkarni)

Medicinal uses

The leaves of *Diplocyclos palmatus* are eaten as a vegetable in Kenya and in South-East Asia. Young and shoots are occasionally eaten as well in South-eaten Asia. In Kenya the roots are used as an antivenin and fruits and leaves to cure stomach-ache. In Thailand stems are used as an expectorant and fruits as a laxative, and in Nepal seeds as a febrifuge. *Diplocyclos palmatus* is grown in Kenya and Zimbabwe as a garden ornamental because of the decorative fruits. (Grubben, 2004)

The plant is acrid, foetid, alterant, depurative and tonic and is useful in cough, flatulence, skin diseases, inflammations and general debility. (T.Pullaiah, 2006)

Seeds - spasmolytic. Used for vaginal dysfunctions, as a fertility promoting drug. Powdered seeds, also roots, are given to help conception in women. Plant is also used in venereal diseases. **(**C.P. Khare)

Use Of Bryonia Laciniosa To Get Male Child

Seeds of *B.laciniosa* resemble to "*Shivling*" symbol of god Siva, were used to cure sterility cases as well as to get male child, in prehistoric age. Fruits are purple in colour with white patches and huge quantity of mucilaginous substances.

Active principle of *B.laciniosa* has got property to regenerate germinal epithelium in both male and females to produce their reproductive organs like ovum and sperm. (H.Panda)

Whole plant is used to treat adenopathy, ague, asthma, bronchitis, carbuncles, cholera, colic, consumption, convulsions, cough, delirium, fertility, headache, megalosplenia, paralysis, phthisis, snake bite.(Bonyadi Rad Ehsan *et al,* 2009)

Fruits bitter in taste; but a common vegetable; also used medicinally for blood sugar.(Kumdranjan Naskar)

Seed extract is taken once a day for 2-3 days during dysentery. (SY Kamble *et al,* 2008)

Seeds are taken with water to promote conception (Dinesh jadhav *et al,* 2006)

Traditional healers use the leaves and the seeds of this plant for treatment of fevers. It is also taken in impotency and used as a tonic. The leaf extract of this plant is also used as a cathartic and in inflammation. (Gupta *et al,* 2003)

Seeds of *Diplocyclos palmatus* is used for Asthma, Cholera, Colic, Constipation, Post natal complaints, promotes fertility in women. (Archana singh *et al* 2012)

The whole plant is used to cure jaundice. 30 ml of whole plant decoction is administered twice a day for 3 to 5 days. (Ratna Manjula *et al,* 2011)

Leaf decoction is taken internally to treat rheumatic pain. (P Pandi Kumar *et al*, 2007)

Seeds crushed in milk are consumed to conceive especially male child. About a cup of it is advised for a fortnight. (Ahirrao *et al*)

Dried fruit powder (one teaspoonful) is mixed with spoonful powder of Sag (*Tectona grandis Linn*). This mixture is taken orally thrice a day for 3 days against urinary complaints. (Dyaneswar P Ghorband *et al* 2002)

Leaf paste is applied to relieve joint pain and rheumatism (S.Ganesan *et al,* 2004)

Sperm count enhancement

One teaspoonful mixture of powdered *Shivlingi Putrada* (*Diplocyclos palmatus)* seeds and *aasoodkand (Withania somnifera)* root (500mg each is taken twice a day with cow milk for six months. (Bhogaonkar *et al,* 2006)

Ovulation enhancement

Ghanfodi Madkafodi (*Cardiospermum helicacabum* L) seeds and *Shivlingi, Putrada* (*Diplocyclos palmatus)* seeds (2 gm each) pounded with one betel leaf is eaten thrice a day for three days. (Bhogaonkar *et al,* 2006)

3. SIDDHA ASPECT OF THE DISEASE

KARAPPAN

Plagues consisting of papules and vesicles are produced on the skin and are surrounded by oedema, blisters and scale -like horny surface, accompanied by colour changes, fissures and water discharge. Itching may or may not be present. *Yugi* has not brought the *Karappan* under the 18 *kuttams* because of its aetiology and characteristic signs and symptoms.

But since it is a disease of the skin it has been brought under this chapter.

Aetiology

Even though the factors cannot be underlined distinctly, this *Karappan* is not caused by pathogenic organisms. This is one of the reasons why Yugi did explain *Karappan* as distinct from *Kuttam*. But there may be secondary infection by microbes on an already *Karappan* affected area.

பெருகும் சோள மிறுங்கும் பெரும்கம்பு
வரகு காருடன் வாழையின் காயொடு
உரைகொள் பாகற் கேளிற்றுமீன் உண்டிடில்
விரிவ தாய்க்கரப் பானுமிகுந்ததே

Foreign authors too accept the above fact:

Most cases of eczema especially in infants are really food allergies; they are reaction of the skin, at a particular time to particular foods. The treatment of such cases lies in prevention and identification of the causative factors and the avoidance of particular types of food.(Justus J.Schifferes)

In Yugi

- Non-vegetarian food
- Pear millet (*Pennisettum typhoideum*)
- Indian millet (*Setavia indica*)
- Little millet (*Paspalum scrobicerlatum*)
- Tuber varieties
- Frequent sexual contacts with elderly women are mentioned as the causative factors of *Karappan*. Similarly Guava, eggs, fish, dried fish, eggplant and pumpkin are shown to cause *karappan*.

The above said products are not allergic to all persons and also they are not allergic to a person at all times of life.

They may be allergic to a particular person at a particular time and not throughout life

Classification:

Yugi has classified *Karappan* into seven main types:

1. *Vatha Karappan*
2. *Kanta Karappan*
3. *Varatchi Karappan*
4. *Thimirvatha karappan*
5. *Kabala Karappan*
6. *PitthaKarappan*
7. *SetthumaKarappan*

In *Pathinen Siddhar Bala Vakatam*, 18 types are referred to as follows:

VathaKarappan, Pittha Karappan, SetthumaKarappan, Ari Karappan, Udhu Karappan, Thulai Karappan, Vedi Karappan, Mantai Karappan, Pori Karappan, Sattaikarappan, Otu karappan, Karum karappan, Senkarappan , Kolli karappan , Thoda karappan , Vaalai karappan, Varal karappan, Veengu karappan .

General Features

To start with, there is itching in the skin followed by papules, vesicles, pustule formation etc…

There is spreading of Plaque and through the discharge of fluid altogether becoming toad skin, it will change the colour of the skin.

The skin may be dry or may be moist with blood discharge with fleshy colour and crust formation.

CLASSIFICATION

Vatha Karappan

The body becomes hot painful, oedematous with fluid accumulation and ulceration. Fingers and joints become immobile and there are varicosity of veins, exopthalmos and dryness of skin.

Kanta Karappan

Head, ears and scalp become painful, oedematous, with thickening of tongue and gooseflesh. There are rigor itching, photophobia and throaty sensation within the throat.

Varatchi Karappan

The body becomes oedematous marked with pricking sensation, pruritus, emaciation of the body, giddiness, fatigue, discharge of fluid, fleshy colour and murmuring.

Thimirvatha karappan

While arising from seated position there is pain in legs, arms and legs and hip and joints become tense , ankylosed. There are paralysis, oedema, and ulceration of the body. Increased micturition, body pain, tremor and heat are present.

There is tremendous pain while walking with oedema of joints, ulceration and fissure formation on the skin.

Kabala Karappan

There are pruritus of ear and eyes, hoarseness of the throat, discharges from eyes, rhinitis, pruritus of scalp, sneezing, palpation on forehead and inflammation of uvula.

Pittha Karappan

Appearance of eyes as though one is sleeping, heat and pain in the stomach, giddiness, fatigue, yellowish discolouration of the body , dysphasia, loss of appetite and a sense of itching on the body.

SetthumaKarappan

Pallor, Hoarseness of voice, slow –pitched voice, dyspnoea on exertion, cough, expectoration, asthma, dependence on others for everything.

*Karappan b*ecomes secondary in Pittha diseases and pramegam.

Karappan in Pittha diseases

Pruritus, papules, sense of heat , hyperpigmentation all over the body, diarrhoea, borborygmi, fits, pain and fatigue of the legs and hip pain.

Karappan in pramegam

Pain in the stomach, mucus discharge, micturition with a sense of heat and burning, ulceration of urethra and mixing of calcium largely in urine, fatigue of limbs and presence of large plagues all over the body.

Prognosis

Vathakarappan, pittha karappan , varatchikarappan, kabalakarappan are cured easily. Others are very difficult to be cured.

நாடி நிதானம்

தானமுள்ள சேத்துமந்தானிளகில்.....

.....கரப்பான் விரணதோடம்

சதகம் 53,

சிறப்பான வாதத்தில் உட்ணந்தானே சேர்திடுகில்.....

.....மதகரி நீர் கரப்பான்.....

சதகம் 56,

General Abstentions:

- The Patient needs rest, sleep, exercise and fresh air.
- Green vegetables, milk and milk products, good nutritional, cooked meat can be given.
- Curry products, spicy foods, *karappan* foods and narcotics must be avoided.

For Children,

- There must be restriction in the quantity of food.
- Intestinal worms have to be treated first.
- Avoidance of constipation is a must.

In washing the affected area

- For blisters – wash with antiseptic solution
- For inflammation – oils
- For ulceration – ointments and liniments
- For crusts – oil application and wash with lukewarm water. Do not use soaps.

Green gram powder and *nalungu ma* can be used. To cure occupational eczema, do advise prevention of contact with the allergic, spurious materials. For example, in dying industry and painting, medical staff and doctors need to prevent contact with streptomycin.

3.5. MODERN ASPECT OF THE DISEASE

SKIN

The skin-the interface between humans and their environment-is the largest organ in the body. It weighs an average of 4kg and covers an area of $2m^2$.It acts as a barrier, protecting the body from harsh external conditions and preventing the loss of important body constituents, especially water. A death from destruction of skin, as in a burn or in toxic epidermal necrolysis and the misery of unpleasant acne, remind us of its many important functions, which range from the vital to the cosmetic.

Function of the Skin

Protection against:

- Chemicals,particles → Horny layer
- Ultraviolet radiation → Melanocytes
- Antigen, heptens → Langerhans cells
- Microbes → Langerhans cells
- Preservation of a balanced internal environment → Horny layer
- Prevents loss of water, electrolytes and macromolecules → Horny layer
- Insulation → Subcutaneous fat
- Sensation → Specialized nerve endings
- Lubrication → Sebaceous glands
- Vitamin D synthesis → Keratinocytes

IMMUNOLOGY OF THE SKIN

The skin is an important immunological organ and normally contains nearly all the elements of cellular immunity; with the exception of B cells. Much of the original research into immunology was done using the skin as a model.

The immunological components of skin can be separated into structures, cells, functional systems and immunogenetics.

Structures

The epidermal barrier is an important example of innate immunity, as most microorganisms that have contact with the skin do not penetrate it. Equally the generous blood and lymphatic supplies to the dermis are important channels through which immune cells can pass to or from their sites of action.

Cells

Langerhans cells of the epidermis are the outermost sentinels of the cellular immune system. These cells plays an important role in antigen presentation.

T Lymphocytes circulate through normal skin. Different types of T cell with differing functions are recognized.

Mast cells (which release histamine and other vasoactive molecules) are normal residents of the dermis, as are macrophages. Both may be recruited to the site during inflammatory reactions.

Keratinocyte may have an immunological function. They synthesize antimicrobial peptides, produce pro inflammatory cytokines.

Hypersensitivity reactions and the skin

Hypersensitivity is the term applied when an adaptive immune response is inappropriate or exaggerated to the degree that tissue damage results. The skin can exhibit all the main types of hypersensitivity response.

Type I (Immediate hypersensitive reaction)

Type II (Antibody-dependent cytotoxicity)

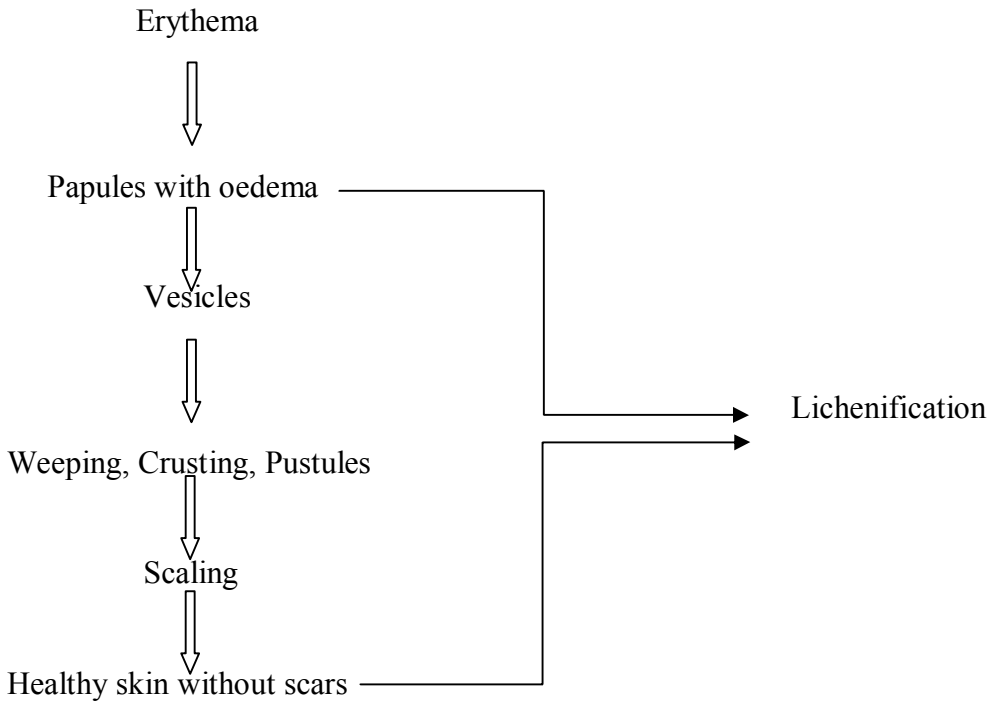
Type III (immune complex)

Type IV (cell mediated or delayed hypersensitive reaction) **(**David J.Gawkrodger)

ECZEMA

Definition

Dermatitis and Eczema is non-contagious inflammation of the skin, Characterized by erythema, scaling, oedema, vesiculation and oozing. Hebra says, "Eczema is what looks like eczema". Dermatitis literally means inflammation of the skin and as such can include all inflammations of the skin except by specific infections. The term 'Eczema' is a Greek word (Ec means out, and Zeo means boil.) The whole word implies 'boil out'.
Eczema is a specific type of allergic cutaneous manifestation of antigen-antibody reaction. It is characterized by superficial inflammatory oedema of the epidermis associated with vesicle formation. Itching varies from mild to severe paroxysms which may even interfere with work and sleep. (P.N.Behl,A.Aggarwal,2007)The nature history of eczema is diagrammatically represented as follows;



Histology

Epidermis may show intercellular oedema (spongiosis) in an acute eczema and acanthosis (hyperplasia of stratum malphigi) hyperkeratosis and parakeratosis (immature keratinization) in the subacute and chronic phases. Dermal inflammatory infiltrate, polymorphonuclear or lymphocytic, may be pronounced in acute eczema, less so in subacute or chronic eczemas.

Classification

Dermatitis is classified into two types. Exogenous and Endogenous dermatitis.

Endogenous dermatitis

Atopic dermatitis

Common, An itchy chronic remitting and relapsing inflammatory skin condition associated with other atopic dermatitis (asthma,hey fever,urticaria) in patient or family. Mode of genetic transmission uncertain. Serum regain, IgE levels may be raised, hence predisposed to anaphylactoid reactions. Delayed hypersensitivity perhaps depressed, hence less prone to developing allergic contact dermatitis. More prone to acquiring viral and some bacterial infections. Dry, generally irritable, skin that may not tolerate extremes of temperature or humitidy such as dry cold, excessive sweating or contact with dust or wool. Patients anxious and sensitive individuals. (Lalit K *et al*)

Epidemiology

Some 5-10% of the population of western Europe develop atopic dermatitis. The disease is familial, with apparent polygenic inheritance.(Wolfram Sterry *et al,*2006) Three distinct or merging phases. Infantile, childhood and adult. Itching, scratching and lichenification are important features.

Each phase could start and end independently.

Infantile phase

Common. Often first born male infant. Onset-about third month, sometimes earlier. Bilaterally symmetrical papulovesicular, exudative and crusted lesions. Cheeks predominantly involved. Later elsewhere-on the extensors of the extremities and trunk. Itching severe and paroxysmal. Secondary bacterial infections common. Spontaneous remissions and relapses. May completely remit by about 2-3 years or may evolve into childhood phase of atopic dermatitis.

Childhood phase

May evolve from the infantile phase or start de novo. Intensely pruritic in the flexures of the elbows and knees, the wrists, ankles and sides of the neck. Symmetrical involvement. Lichenified and excoriated lesions.

Adult phase

Relatively uncommon. May evolve per se or from atopic dermatitis of infancy or childhood. Lichenified plaques, often in the flexures. Extensor aspects of the extremities occasionally involved. Itching a dominant complaint and the patients thus more prone to develop lichen simplex chronicus.

Nummular Eczema

A morphological diagnosis. Discoid or coin shaped lesions of uncertain, possibly multiple, etiology.A number of unrelated factors such as atopy, infection, autosensitization, physical trauma, particularly on a dry asteatitic skin may be responsible.

Erythematous, edematous discoid plaques of itchy, papulovesicular lesions which exude serous discharge and form crusts. Dorsa of the hand and extensor aspect of

upper or lower extremities preferentially affected. Bilateral but often asymmetrical. Relapsing and remitting. Relapses often abrupt in onset and frequent in winter.
Dry discoid dermatitis: A nonexudative variant of Nummular eczema. Round or oval, dry, scaly plaques on extensors of extremities. Variable, often recurrent and chronic course.

Pompholyx

Acute bilateral symmetrical vesicular eruption of the palms and soles. Multifactorial; atopic or other endogenous eczema. More common in summer. Hyperhidrosis a common, but causally unrelated, association. Young adult of both sexes affected. Itchy or painful deep seated vesicular(sago-grain like) lesions on the palms, sides of the fingers and soles. Occationally bullous or pustular lesions.

Seborrhoeic dermatitis

Characterised chiefly by its distribution. Characteristic seborrhoeic look-oily skin with patulous, prominent follicular orifices. Sites of predilection:Scalp, retroauricular folds, eyebrows, nasolabial folds, beard area, interscapular and presternal regions, axillae, pubic region, groins, umbilicus, and folds under pendulous breasts. Generally chronic with remissions and exacerbations.Patients predisposed to pyococcal infections.

Stasis Eczema

Middle aged individual with compromised venous return. Related to long hours continued standing. Medial aspect of ankle and lower legs involved. Slate-grey pigmentation. Later oedema, itching, acutely exudative and crusted or scaly and lichenfication areas; associated with obvious varicose veins or other evidence of venous stasis.

Exogenous dermatitis

Irritant contact dermatitis

Common, non-immunological dermatitis, secondary to contact with an irritant substance in ‘adequate’ concentration for a ‘sufficient’ length of the time. Individual with dry skin more prone. Acute irritant dermatitis sharply limited to the area of contact.Similar in morphology to the acute eczemas-Papules, vesicles or pustules on an erythematous background. Heals with hyper or hypo pigmentation. Strong irritants may

cause necrosis or ulcers that heal with scars. Cumulative insult dermatitis due to repeated contact with weak irritants, classical example: 'housewives' dermatitis. Slow onset.

Allergic contact dermatitis

A common dermatological problem, more frequent in the industrialized world. Type IV delayed type hypersensitivity (DTH) response. Simple chemicals (haptens) become complete antigens on combining with a carrier, generally epidermal protein. Airborne contactants affect exposed sites-face, particularly the eyelids, neck, hands and forearms. Textile dermatitis-axillae, flexures of elbows, thighs or other areas in intimate contact with clothing. Occupational dermatitis-the hands and other exposed parts. Metal dermatitis-sites of contact with jewellery; watch straps on the wrist. *Parthenium hysterophorus* is a common contactants.

Photocontact Allergic Dermatitis

Several patients with parthenium dermatitis exhibit photoaggravation of a purely allergic dermatitis or develop the dermatitis only on exposure to light. Sites of airborne allergy thereby modified.

Infective Dermatitis

Acute eczematous reaction to contact with purulent discharge from a pyococcal lesion; a boil, a discharging ear, an infected scabies or pediculosis. Exuding, crusted, well or ill-defined plaques of vesiculopustular lesions. Discoid or bizarre shaped. Auto-inoculation common.

Asteatotic Eczema

Elderly individual with dry xerotic skin affected. Irregular or patches of superficially fissured, dry, scaly, and mildly crusted lesions on the extensors of the legs, dorsa of the hands and the trunk. Variable itching. Frequent baths, use of soap, detergents, dry and cold climates worsen.

Napkin Dermatitis (Diaper dermatitis)

Less common in developing countries where infants frequently stay without occlusive napkins. Common in the developed world. Use of occlusive diapers and lack of

frequent changes predispose. Multifactorial etiology-irritation with feces and urine or the presence of irritant detergents in the napkins.

Lip-licking dermatitis

Not uncommon; seen in children with a habit of licking their lips and around. Rule out atopic diathesis. Well defined, scaly lesions around the mouth. (Lalit K *et al)*

INVESTIGATIONS

Specific IgE, Patch test, Prick test

3.6. LATERAL RESEARCH VIEW OF THE PLANT

Effects of *Bryonia laciniosa* seeds on sexual behaviour of male rats.

Ethanolic extract of seeds of *Bryonia laciniosa* Linn was administered orally to groups of male albino rats at the dose levels of 50, 100, and 150 mg kg(-1) body weight per day for 28 days. The changes in sexual behaviour, reproductive organ weights, histology of testis and epididymis, epididymal sperm density, and androgenic hormone levels were evaluated. The sexual behaviour parameters studied such as mount frequency, intromission frequency, mount latency, intromission latency were evaluated. Increase in body weight as well as weight of testis, prostate, seminal vesicle, and epididymis was noticed. Transverse sections of testis exhibited increased spermatogenesis and a significant increase in sperm count in epididymis. The fructose content of seminal vesicle was also increased. The extract treatment also brought a significant increase in serum testosterone and luteinizing hormone levels. The studies clearly reflect androgenic activity of the extract and its effects on hypothalamic pituitary gonadal axis. (Chauhan *et al,* 2010)

In Vitro cytotoxicity of *Bryonia laciniosa*(Linn.) Naud. On human cancer cell lines

The water, methanol and chloroform extracts of *B.laciniosa* leaves were tested on human cancer and normal cell lines using three in vitro cytotoxicity assays i.e cell viability, SRB and clonogenic potential. The effect was compared with that of standard anticancer drugs doxorubicin and vincristine. Activation of caspase-8 and caspase-3 enzymes was assessed to evaluate the effect of extract on induction of apoptosis in cells.

Of the different extracts, the aqueous extract demonstrated maximum cytotoxicity to cancer cells. The IC50 value was estimated to be 18 μg/mL. Nearly all cancer cells could be killed by the leaf extracts of *B.laciniosa* in vitro, where as small fraction of cells from cancer cell lines showed resistance to doxorubicin even at concentration much higher than IC50. Results of caspase assay demonstrated activation of both caspase-8 and caspase-3 enzymes indicating induction of apoptosis in *B.laciniosa* leaf extract treated cells. The results thus show that aqueous extract of *B. laciniosa* leaves possess cytotoxicity to cancer cells and are able to kill all cancer cells without leaving residual population. (Alpana S Moghe *et al*, 2011)

4. MATERIALS AND METHODS

4.1. PREPARATION OF THE DRUG

Collection and authentication of the material:

The plant material used in this study was collected from Anthiyur Hills, Erode district, Tami Nadu, India. and authenticated by Botanist, Central Research Institute for Siddha and Siddha experts of *Gunapadam* Department. The drug "***Aivaeli***" was selected from the classical Siddha literature *Pathartha Guna Villakam* written by *Kannusamiyam Pillai.*

Preparation of *Aivaeli samoola Chooranam*:

The fresh whole plant of *Aivaeli* of 10 Kg was thoroughly cleaned to eliminate soil particles and impurities. Then the plant was cut into small pieces and dried in shade. Afterward they were finely powdered. The resultant powder of 7 kg was subjected to sieve with white cotton cloth to get finest physical form. (*Vasthirakayam)*

Purification of Chooranam:

The *Chooranam* was moistened with cow's milk. Pots were filled with milk and water of equal ratio to nearly ¾ its volume. The mouth of the pot was roofed and tied with white cotton cloth. The *Chooranam* moistened by milk was placed on top of the tied cloth. The mouth of the pot was closed with another mud pot. The gap between the two mud pots was tied with a wet cloth to prevent evaporation. Then this pot was subjected to heat and boiled until milk level in lower pot gets reduced to ¼ volumes. Then the powder was taken, dried, powdered finely and preserved for usage.

Preservation:

The purified *Chooranam* was stored in a clean, air tight glass container.

Life span **:** 3 Months.

Administration of the drug:

Form of the medicine	:	*Chooranam*
Route of Administration	:	Enteral
Dose	:	1 - 2 gms
Anubanam (Vehicle)	:	Sugar
Administration	:	Two times a day; after food

4.2. STANDARDISATION OF *AIVAELI SAMOOLA CHOORANAM*:

Standardization of drugs means evidence of its characteristics and determination of its quality, effectiveness and aptness to be used as medicine. Standardization of plant drug is based on the concentration of their active principles, physical and chemical standards. Plant drug has been standardized on the basis of physical characteristics, organoleptic properties, and phyto-chemical properties. The process of standardization can be achieved by stepwise studies.

Collection and identification of plant:

The plant material *viz*., root, stem, leaf, flower, fruit and seeds of *Diplocyclos palmatus*. Belongs to the family Cucurbitaceae were collected from Anthiyur Hills, Erode district, Tamilnadu. The plant was identified with the help of Botanist, Central Research Institute for Siddha, Chennai-106 and by the Siddha experts of Gunapadam Department and a voucher specimen is kept in the Herbarium, Department of *Gunapadam*, Govt.Siddha Medical College, Arumbakkam Chennai-106.

4.2.1. PHARMACOGNOSTIC STUDY

Collection of specimens

The plant specimens for the proposed study were collected from Anthiyur hills, Erode district, Tamil Nadu. Care was taken to select healthy plants and normal organs. The required samples of different organs were cut and removed from the plant and fixed in FAA (Farmalin-5ml+ Acetic acid-5ml + 70% Ethyl alcohol-90ml).After 24 hrs of fixing, the specimens were dehydrated with graded series of tertiary –Butyl alcohol as per the schedule given by Sass, 1940. Infiltration of the specimens was carried by gradual addition of paraffin wax (melting point 58-60 C) until TBA solution attained super saturation. The specimens were cast into paraffin blocks.

Sectioning

The paraffin embedded specimens were sectioned with the help of Rotary **Microtome.** The thickness of the sections was 10-12 μm. Dewaxing of the sections was by customary procedure (Johansen, 1940). The sections were stained with **Toluidine blue** as per the method published by O'Brien et al. (1964). Since **Toluidine blue** is a polychromatic stain. The staining results were remarkably good; and some **cytochemical** reactions were also obtained. The dye rendered pink colour to the **cellulose** walls, blue to the **lignified** cells, dark green to suberin, violet to the mucilage, blue to the **protein** bodies etc. wherever necessary sections were also stained with **safranin** and **Fast-green** and IKI(for Starch)

For studying the stomatal morphology, venation pattern and trichome distribution, **paradermal sections** (sections taken parallel to the surface of leaf) as well as **clearing** of leaf with 5% sodium hydroxide or epidermal peeling by partial maceration employing Jeffrey's maceration fluid (Sass, 1940) were prepared. Glycerine mounted temporary preparations were made for macerated/cleared materials. Powdered materials of different parts were cleared with Naoh and mounted in glycerine medium after staining. Different cell component were studied and measured.]

Photomicrographs

Microscopic descriptions of tissues are supplemented with micrographs wherever necessary. Photographs of different magnifications were taken with **Nikon labphoto 2** microscopic Unit. For normal observations **bright field** was used. For the study of **crystals, starch grains** and **lignified** cells, **polarized** light was employed. Since these structures have **birefringent property**, under polarized light they appear bright against dark background. Magnifications of the figures are indicated by the scale-bars. Descriptive terms of the anatomical features are as given in the standard Anatomy books (Esau, 1964).

4.2.2. ORGANOLEPTIC EVALUATION

The organoleptic characters of the sample were evaluated (Siddiqui *et al).* Organoleptic evaluation refers to evaluation of the formulation by colour, odour, taste and texture etc.

4.2.3. PHYSICO-CHEMICAL INVESTIGATIONS

Physico-chemical studies like total ash, water soluble ash, and acid Insoluble ash, water and alcohol soluble extract, loss on drying at 105°C and pH have been done at Siddha Central Research Institute –chennai-106 as per the WHO guide lines.

Determination of Total Ash:

Incinerate about 2 to 3 g accurately weighed, of the ground drug in a tared platinum or silica dish at a temperature not exceeding 450º until free from carbon, cool and weigh. Calculate the percentage of ash with reference to the air-dried drug.

Determination of Acid Insoluble Ash:

Boil the ash obtained for 5 minutes with 25 ml of dilute hydrochloric acid; collect the insoluble matter in a Gooch crucible or on an ash-less filter paper, wash with hot water and go up in flames to constant weight. Analyze the percentage of acid-insoluble ash with reference to the air dried drug.

Determination of Alcohol Soluble Extractive:

Grind 5 g of the air dried drug, coarsely powdered, with 100 ml of Alcohol of the specified strength in a closed flask for twenty-four hours, shaking frequently during six hours and allowing standing for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tarred flat bottomed shallow dish, and dry at 105º, to constant weight. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

Determination of Water Soluble Extractive:

Proceed as directed for the determination of Alcohol-soluble extractive, using Chloroform water instead of ethanol.

Determination of Moisture Content (Loss on Drying):

Procedure set forth here determines the amount of volatile matter (i.e., water drying off from the drug). For substances appearing to contain water as the only volatile constituent, the procedure given below, is appropriately used. Place about 10 g of drug (without preliminary drying) after accurately weighing (accurately weighed to within 0.01 g) it in a tared evaporating dish. For example, for underground or un powdered drug,

prepare about 10 g of the sample by cutting shredding so that the parts are about 3 mm in thickness.

After placing the above said amount of the drug in the tared evaporating dish dry at 105º for 5 hours, and weigh. Continue the drying and weighing at one hour interval until difference between two successive weighing corresponds to not more than 0.25 per cent. Constant weight is reached when two consecutive weighing after drying for 30 minutes and cooling for 30 minutes in a desiccators, show not more than 0.01 g difference.

Determination of pH:

1% solution of plant drug was prepared in distilled water and pH was determined using pH meter SYSTRONICS DIGITAL pH METER, MK VI.

TLC estimation of *Aivaeli samoola chooranam*:

Thin-layer chromatography is a technique in which a solute undergoes distribution between two phases, stationary phase acting through adsorption and a mobile phase in the form of a liquid. The adsorbent is a relatively thin, uniform layer of dry finely powdered material applied to a glass, plastic or metal sheet or plate. Glass plates are most commonly used.

Identification can be effected by observation of spots of identical Rf value and about equal magnitude obtained, respectively, with an unknown and a reference sample chromatographed on the same plate. A visual comparison of the size and intensity of the spots usually serves for semi-quantitative estimation.

Solvent system:

Toluene : Ethyl acetate (5:0.5).

TLC plate:

Aluminium plate pre-coated with silica gel $60F_{254}$ of 0.2 mm thickness (Merck).

Developing chamber:

Camag's twin trough chamber.

Visualizing reagent:

Vanillin-sulphuric agent.

Extract Preparation:

4 g of the *chooranam* was soaked overnight in chloroform. Boiled on a water bath for 10 mints, filtered and concentrated to 10 ml.

Procedure:

The extract was applied on the TLC using capillary and developed in the solvent system. The developed TLC plate was air dried, dipped in vanillin-sulphuric acid reagent and heated in an oven at 105°C until the development of coloured spots.

4.2.4 PHYTO CHEMICAL EVALUATION OF PLANT

Phytochemicals are chemical compounds that take place naturally in plants. They are answerable for color and organoleptic properties and may have biological or pharmacological activity is attributed. The powdered *Aivaeli samoola chooranam* is subjected to following process.

Test for Flavonoids (Shinoda test)

Substance is dissolved in alcohol, added with magnesium bits and concentrated hydrochloric acid. On heating over a water bath, the appearance of magenta colour shows the presence of flavonoids.

Triterpenoids (Noller's Test)

To few mg of extract, add tin and thionyl chloride and heat in water bath. Purple colour indicates the presence of tritepenoids.

Test for Proteins (Biuret test)

To the sample solution in a test tube, add sodium hydroxide solution and then add a few drops of very dilute (1 %) copper II sulphate solution and mix gently. Appearance of purple colour indicates the presence of protein.

Test for Anthraquinones

Few milligram of crude powder is shaken with 10 ml of benzene and filtered. To this filtrate, 0.5 ml of 10 % ammonia solution is added and the mixture is shaken well and the presence of the violet colour in the layer phase indicates the presence of the anthraquinone.

Test for Alkaloids (Dragendorff's Test)

Few mg of extract in separate test tube was warmed with 2% Sulphuric acid for 2 minutes. And it was filtered in separate test tube and few drops of Dragendorff's reagent were added. The presence of orange red precipitates indicates the presence of alkaloids.

Test for Saponins

To few mg of extract distilled water is added and shaken well. The formation of foam indicates the presence of saponin.

Test for Steroids (Lieberman Burchard Test)

To few mg of the extract 2 ml of chloroform is added in a dry test tube. Few drops of acetic acid is added, heated and few drops of acetic anhydride and 2 drops of concentrated sulphuric acid are added. The green colour indicates the presence of steroid.

Test for Coumarin

Extract is shaken with 10% sodium hydroxide. Yellow colour shows the presence of coumarin. Add concentrated sulphuric acid, original extract colour is regenerated.

Test for Acids

Extract is treated with sodium bicarbonate solution. Effervescence shows the presence of acid.

4.2.5 PRELIMINARY CHEMICAL ANALYSIS

Preparation of Extract :

Add 5 gm of the sample to 50ml of distilled water. Boil the solution for 20 minutes, cool and then filter. Use the Extract for the following tests.

S.No	Experiment	Observation	Inference
1.	**Test for reducing Sugar :** To 5ml of Benedicts qualitative reagent, add 10 drops of extract, then boil for two minutes	Green / Yellow / Red precipitate	Presence of Reducing Sugar
2.	**Test for Starch :** To 5 ml of extract add 2ml of acetic acid and then add few drops of N/50 Iodine Solution.	Blue Colour	Presence of Starch
3.	**Test for Proteins :** To 2 ml of extract, add 2ml of 5% Sodium Hydroxide mix and add 2 drops of Copper Sulphate Solution.	Violet or Purple Colour	Presence of Proteins
4.	**Test for amino Acid :** Place 2 drops of extract on a filter paper and allow to dry well. Then spray 1% ninhydrin over the same and allow to dry.	Violet Colour	Presence of Amino Acid
5.	**Test for Albumin :** To 2 ml of extract, add 2ml of Esboch's reagent.	Yellow precipitate	Presence of Albumin
6.	**Test for Phosphate :** To 2ml of extract, add 2ml of ammonium Molybdate solution and 2ml of concentrated Nitric Acid.	Yellow precipitate	Presence of Phosphate
7.	**Test for Sulphate :** To 2 ml of extract add 2ml of 4% ammonium oxalate solution.	White precipitate	Presence of Sulphate
8.	**Test for Chloride :** Add 2ml of extract to dilute nitric acid till the effervescence ceases. Then add 2 ml of Silver Nitrate Solution.	Cloudy White precipitate	Presence of Chloride
9.	**Test for Iron :** To 2ml of extract, add 2ml of ammonium thio cynate solution and add 2ml of concentrated Nitric Acid.	Red Colour	Presence of Iron
10.	**Test for Calcium :** To 2 ml of extract, add 2 ml of 4% ammonium Oxalate Solution.	White precipitate	Presence of Calcium

11.	**Test for Sodium :** Make a paste with 2 pinches of the sample with Hcl and Introduce it into the blue flame.	Yellow Flame	Presence of Sodium
12.	**Test for Potassium :** Add a pinch of the sample to 2 ml of Sodium Nitrate Solution. Then add 2ml of Cobal Nitrate in 20% acetic acid.	Yellow precipitate	Presence of Potassium
13.	**Test for Zinc :** To 2ml of extract, add few drops of Sodium Hydroxide.	White precipitate	Presence of Zinc
14.	**Test for Magnesium :** To 2ml of extract, add few drops of Sodium Hydroxide Solution	White precipitate	Presence of Magnesium
15.	**Test for Alkaloids :** a. To 2ml of extract, add 2ml of Potassium Iodide Solution b. To 2ml of extract add 2ml of Picric Acid. c. To 2 ml of extract add 2ml of Phosphotunqstic Acid.	Red colour Yellow colour White precipitate	Presence of Alkaloids Presence of Alkaloids Presence of Alkaloids
16.	**Test for Tannic Acid :** To 2ml of extract add 2 ml of Ferric Chloride Solution	Black precipitate	Presence of Tannic Acid

PRECLINICAL EVALUATION OF THE TRIAL DRUG

Swiss albino mice of both sex weighing between (18-22 g) and Albino Wistar rats of the either sex (180-200 g) were grouped and housed in polyacrylic cages and maintained under standard laboratory conditions (temperature 24-28°C, RH, 60-70% and 12 h light dark cycles) and were fed with standard pellet diet supplied by Sai durga foods, bangalore, India, and water *ad libitum*. All experiments involving animals were done according to OECD guidelines, after getting the approval of the institute animal Ethics committee. (XIII/VELS/PCOL/56/2000/CPCSEA/IAEC/08.08.2012).

4.3. TOXICOLOGICAL STUDY OF THE DRUG:

Acute toxicity study

The trial drug *Aivaeli samoola chooranam* was subjected to acute toxicity studies in order to determine the safety of drug

Swiss albino mice were treated with foxed doses of *Aivaeli Samoola Chooranam* 2000 and 5000mg/kg in 2% CMC as suspension (p.o) respectively. The mortality rate with a 24 h period was determined according to the OECD 425 method.

4.4. PHARMACOLOGICAL ACTIVITY:

4.4.1. ANTI-HISTAMINIC ACTIVITY OF AIVAELI SAMOOLA CHOORANAM

Drugs And Stock Solution

Drug used was Histamine diphosphate (Sigma Chemical, USA). Histamine dihydrochloride was dissolved in distilled water and desired concentrations were prepared. The test drug *Aivaeli Samoola chooranam* concentration was 100microgram per ml prepared by suspending with 2% CMC and then the volume was adjusted to 10 ml with normal saline for making the concentration of 100 µg/ml in distilled water.

Animals

Male albino guinea pig weighing 350– 400g was kept in fasting condition 18 hours prior to commencement of experiment and given water ad libitum. It was housed under standard laboratory conditions of temperature (25 ± 2°C) and 12/12 hr light/dark

cycle and then sacrificed by a blow to the head and exsanguinated as per CPCSEA recommended guidelines. (XIII/VELS / PCOL /56 /2000/ CPCSEA /IAEC /08.08.2012).

In-vitro antihistaminic study

Guinea pig was sacrificed and a segment from ileum (3cm) was dissected from the terminal ileum and mounted in an organ bath containing Tyrode solution (10 ml) between two stainless steel hooks under 0.5 to 1 g initial tension. The lower hook was fixed at the bottom of the organ bath and upper one was connected to an isotonic transducer. The Tyrode solution composition (pH 7.4) was (concentration in gm/lit.) NaCl 8.0, KCl 0.2, $CaCl_2$ 0.2, $MgCl_2$ 0.1, $NaHCO_3$ 1.0, NaH_2PO_4 0.05, and Glucose1.0 gm/liter. It was continuously aerated and maintained at 37 ± 0.5ºC The equilibrium period was 60 min and the bath solution was refreshed every 15 min. After equilibrium period, a dose response curve for histamine in variant molar concentrations, by maintaining 45 min time cycle.

Statistical Analysis

Ileum contractions induced by agonist were assumed as 100% and reductions induced by test drug calculated. Percentage of ileum contraction was expressed as mean ± SEM. Results were analyzed using one-way analysis of variance (ANOVA). Probability value less than 0.05 were considered as significant.

4.4.2. ANTI-INFLAMMATORY ACTIVITY OF AIVAELI SAMOOLA CHOORANAM

Animals

Swiss albino mice of both sex weighing between (18-22 g) and Albino Wistar rats of the either sex (180-200 g) were grouped and housed in polyacrylic cages and maintained under standard laboratory conditions (temperature 24-28°C, RH, 60-70% and 12 h light dark cycles) and were fed with standard pellet diet supplied by Sai durga foods, bangalore, India, and water *ad libitum*. All experiments involving animals were done according to OECD guidelines, after getting the approval of the institute animal Ethics committee (XIII/VELS /PCOL /56/2000 /CPCSEA /IAEC /08.08.2012).

Chemicals and Drugs used

Formalin (S. D. Fine Chemicals Limited, Bombay), acetylsalicylic acid (Bayer AG), sodium carboxy methyl cellulose (Aldrich), used as drugs or chemicals.

Formalin induced oedema

Anti-inflammatory activity was evaluated by formalin induced paw oedema method. Animals of all the groups were injected with 0.1 mL of 1% formalin in 0.9% normal saline, in the right hind foot under the plantar region.. Group I animals (formalin control) received a suspension of 2% of CMC p.o., 30 min prior to formalin injection. Group II and Group III received p.o., 250 and 500 mg/kg of *Aivaeli Samoola Chooranam* respectively, 30 min prior to formalin injection. Group IV, the standard reference group was given p.o., an aqueous solution of Aspirin (100 mg/kg), 30 min prior to formalin injection. The paw volume or the inflammation was quantified in terms of ml i.e. replacement of mercury by edema using a plethysmometer just before and 30, 60, 120minutes after formalin injection. The percentage inhibition of the oedema was calculated for each which respect to the vehicle treated control group.

Statistical Analysis

Values for anti-inflammatory activity were expressed as "mean increase in paw volume ± SEM. The results were analyzed for statistical significance using one-way ANOVA followed by Dunnet 't' test. $P<0.05$ was considered significant.

4.4.3. ANTI MICROBIAL ACTIVITY OF AIVAELI SAMOOLA CHOORANAM

Antimicrobial assay-Isolation and maintenance of cultures

Esherichia coli and Bacillus subtilis were extracted from food stuffs by serial dilution agar plate method. In this method, serial dilutions of samples obtained from food stuffs were prepared and aliquots from each dilution were added to the plates containing nutrient agar to allow the growth of microbes. All the bacterial isolates were identified by cultural, morphological biochemical characteristics (Gram and endospore staining). The plates were kept in an incubator at 37ºC. The slants were prepared from the pure cultures obtained and kept in the refrigerator at 4^0C for further use.

Standardization of inoculums

The microbial inoculum was standardized at 0.5 McFarland. In microbiology, McFarland standards are used as a reference to adjust the turbidity of bacterial suspensions so that the number of bacteria will be within a given range. Original McFarland standards were made by mixing specified amounts of barium chloride and sulfuric acid together. Mixing the two compounds forms a barium sulfate precipitate, which causes turbidity in the solution. A 0.5 McFarland standard is prepared by mixing 0.05 ml of 1.175% barium chloride dihydrate ($BaCl_2 \cdot 2H_2O$), with 9.95 ml of 1% sulfuric acid (H_2SO_4). The standard could be compared visually to a suspension of bacteria in sterile saline or nutrient broth.

Antimicrobial Activity

The antimicrobial activity was determined using the hole-in-plate bio assay procedure. The pure cultures of the microorganisms were inoculated onto Muller-Hilton nutrient broth incubated at temperature of 37°C for 24 hours. Using a sterile cork-borer of 5mm diameter, three holes were made into the Petri dishes seeded with bacterial culture. Concentrations of 25, 50 and 100µg/ml solution were reconstituted in distilled water and transferred into the wells. The plates were incubated at temperature of 37°C for 18 hours. S. aureus, E. coli, Salmonella typhi, P.aurigunosa, St. pyogenes, and Candida albicans were used as the test microorganisms. All microbial cultures were maintained on nutrient agar slants at temperature of 4ºC and sub cultured onto nutrient agar broth for 24 hours prior to testing.

The plates were kept for 30 min at room temperature to allow diffusion of the test drug, and then were incubated at temperature of 37º C for 18 hours. After the incubation period, the zones of inhibition will be measured using a caliper. Studies were performed in triplicates and the mean value was calculated.

Agar well diffusion method

Antimicrobial activity of *Aivaeli Samoola Chooranam* was tested using agar well diffusion method. 200µl of bacteria was aseptically introduced and spread using cotton swabs on surface of gelled sterile Muller Hilton agar plates. A well of about 6.0mm diameter with sterile cock borer was aseptically punched on each agar plate. 50µl of the

ASC were introduced into the wells in the plates. A negative control well was too made with 50µl of the sterile distilled water. Plates were kept in laminar flow for 30 minutes for pre diffusion of *Aivaeli Samoola Chooranam* to occur and then incubated at 37ºC for 24 hours. Resulting zone of inhibition was measured.

For determination of antimicrobial activity of three doses of *Aivaeli Samoola Chooranam,* different bacterial and fungal strains were used by agar ditch method. The pathogenic cultures were swabbed separately in each air dried pre-incubated Nutrient Agar and Sabouraud Dextrose Agar plates with help of sterile cotton swabs. Ditches were prepared in agar plates with the help of surface sterilized borer. After boring the Aivaeli Samoola Chooranam suspension of different concentrations were added separately to the ditches (50µl). The plates were incubated at 37^0C. Controls were maintained. After 24 h diameter of clear zone produced around the ditches were measured to the nearest mm with the help of the micro scales.

4.5 CLINICAL ASSESSMENT OF AIVAELI SAMOOLA CHOORANAM:

Eczema is one of the skin ailments which affect this beauty and protective function of skin. Thus it affects physically and mentally. Diseases of the skin account for a great deal of misery, suffering, incapacity and economic loss. Besides this, they are a great handicap in the society, because they are visible.

Objectives:

To explore the efficacy of *Aivaeli samoola chooranam* in patients with Eczema.*(Karappan)*

Design of the Study:

The Open clinical trial – phase II B

Study Centre:

Arignar Anna, Government Hospital of Indian Medicine and Homeopathy, Arumbakkam, Chennai – 106.

Study Participants:

Both men and women and members of all races and ethnic groups were eligible for this trial. Treatment was administered on an *inpatient/outpatient* basis. The patients had been selected from the In-patient and Out-patient department of Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Chennai – 106.

Number of Subjects:

Number of participants- 50

Registration Process:

To register a patient, the following documents should be completed by the investigator.

- Copy of required laboratory tests
- Signed patient consent form
- Other appropriate forms (e.g., Trial pro-forma).

The investigator verified eligibility and assigned a patient study number, drug dose and register the patient on the study.

Selection:

50 patients from both sexes of various age groups were selected for clinical trial. Among 50 patients 40 patients were treated as out-patients, 10 patients were treated as in-patients. The selection was based on the inclusion and exclusion criteria. They were clinically diagnosed on the basis of siddha principles with modern laboratory findings.

Criteria for Selection:

Including Criteria:

The particular signs and symptoms like

1. Itching
2. Erythema
3. Vesicles
4. Pastules
5. Oozing
6. Oedema
7. Allergic tendency
8. Crusting
9. Scaling

Excluding Criteria:

1. Herpes zoster
2. Neurodermatitis
3. Psoriasis
4. Skin cancer
5. Tinea pedis
6. Scabies

Criteria for Withdrawal:

Patients were removed from study when any of the criteria listed below applies. The reason for study removal and the date the patient was removed must be documented in the Case Report Form.

- Irregular medication.
- Any adverse reactions during the study period.

- Patients who are all not following the diet restrictions
- Patient decides to withdraw from the study, or Unwanted prolonged illness during the study period

Investigation:

For all the cases full clinical data were recorded and they were diagnosed on the basis of *SIDDHA* principles i.e. *Envagai Thrvugal*, *Ezhu Udal Thathukkal* Etc.

All the patients under study were subjected to blood investigations for TC, DC, ESR, Hb and Blood sugar were investigated.

Urine test for albumin, sugar, deposits and motion test for ova, cysts were done.

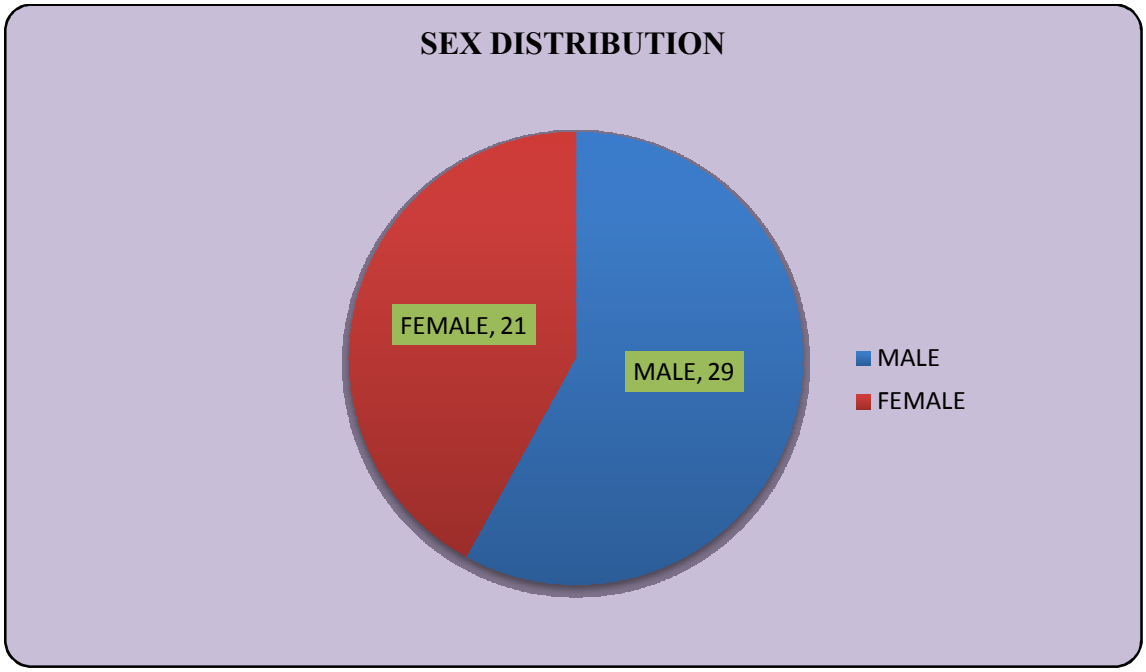
The disease *KARAPPAN* was confirmed in the patients by means of Serum Ig E, skin biopsy and clinically.

Criteria for Assessment of Response to Therapy:

1) Marked Relief : 95% relief in signs and symptoms and marked normalcy of pathological investigations.
2) Moderate Relief : 80% – 90% relief in the presenting signs and symptoms and moderate normalcy of pathological investigation.
3) Mild Relief : 70% - 80% relief signs and symptoms, mild normalcy of pathological investigation.
4) Poor Relief : below 60% relief of signs and symptoms and no marked changes in pathological investigations.

Table no-1 SEX DISTRIBUTION

SL. NO	SEX	NO. OF PATIENTS	PERCENTAGE (%)
1.	Male	29	58
2.	Female	21	42
TOTAL		50	100



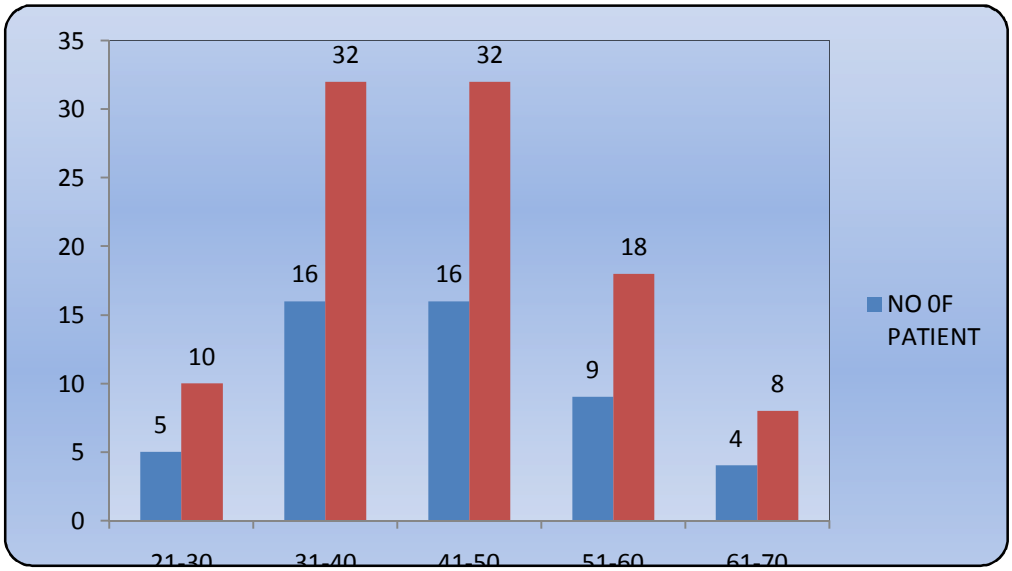
Inference:

Among 50 patients,

- 29 patients were male
- 21 patients were female

Table No-2 AGE WISE DISTRIBUTION

SL. NO	AGE IN YEARS	NO. OF PATIENTS	PERCENTAGE (%)
1.	21-30	5	10
2.	31-40	16	32
3.	41-50	16	32
4.	51-60	9	18
5.	61-70	4	8
TOTAL		50	100



Inference:

5 patients belongs to the age group of 21-30

16 patients belongs to the age group of 31-40

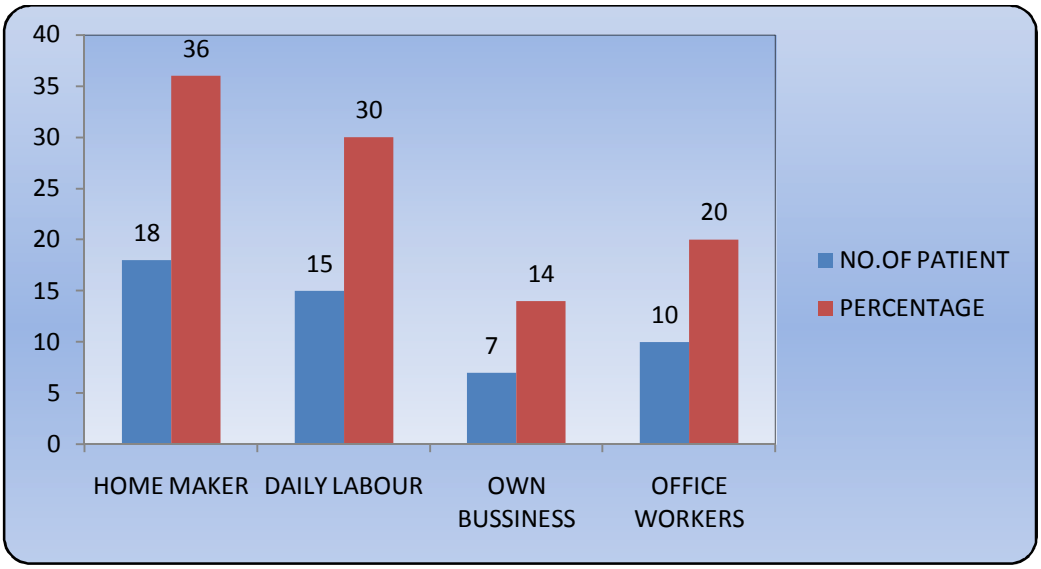
16 patients belongs to the age group of 41-50

9 patients belongs to the age group of 51-60

4 patients belongs to the age group of 61-70

Table No-3 OCCUPATION STATUS

SL. NO	OCCUPATION	NO. OF PATIENTS	PERCENTAGE (%)
1.	Home makers	18	36
2.	Daily Labour	15	30
3.	Own Business	7	14
4.	Office Workers	10	20
TOTAL		50	100



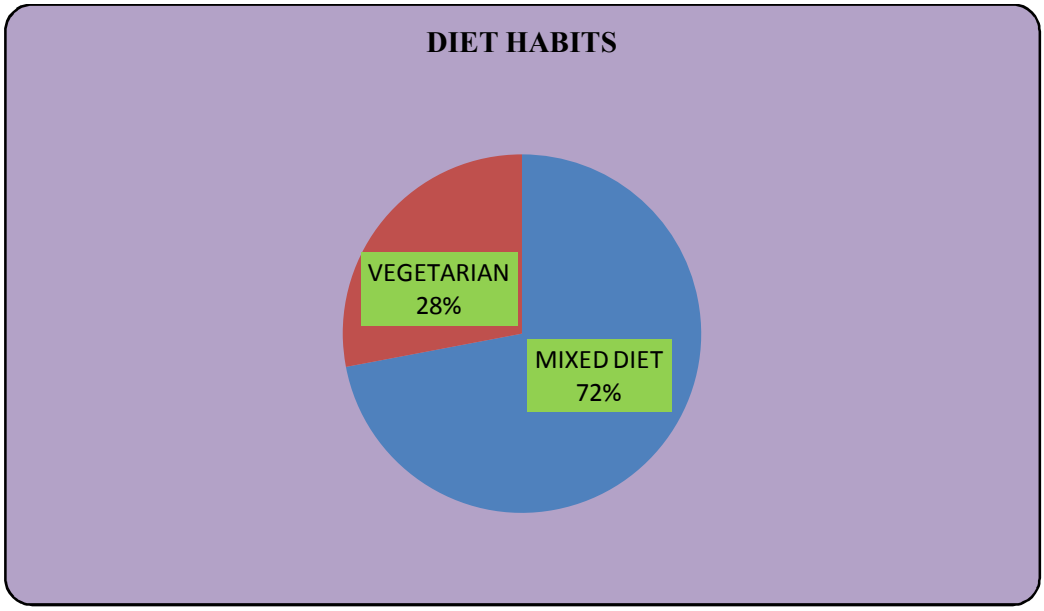
Inference:

Among 50 patients

- 18 patients are Home makers.
- 7 patients are own business.
- 10 patients are Office workers.
- 15 patients are Daily Labour

Table No-4 DIET HABITS

S.NO	DIET	NO OF PATIENT	PERCENTAGE
1.	MIXED	36	72
2.	VEGETARIAN	14	28



Inference:

36 patients are mixed diet

14 patients are vegetarian diet

CLINICAL STUDY ON *AIVAELI SAMOOLA CHOORANAM* FOR KARAPPAN (O.P)

Sl.No.	O.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
1.	7439	SHANTHAM	55/F	Itching, erythema, lichenification, pustules, oozing, varicose vein present	18.06.2012 to 06.08.2012	Marked
2.	099	KAVITHA	37/F	Itching, erythema, lichenification, pustules, oozing, present	25.06.2012 to 30.07.2012	Mild
3.	782	RADHA BAI	69/F	Itching, erythema, lichenification, pustules, oozing, varicose vein present	27.06.2012 to 12.08.2012	Marked
4.	3189	SANGEETHA	28/F	Itching, erythema, lichenification, pustules, oozing, present	07.07.2012 to 09.08.2012	Marked
5.	3684	ANANDH	42/M	Itching, erythema, lichenification, pustules, oozing, present	09.07.2012 to 15.07.2012	Marked
6.	5661	SUNDHARESAN	55/M	Itching, erythema, lichenification, pustules, vesicle, varicose vein present	17.07.2012 to 07.09.2012	Mild
7.	5819	SAKTHI	35/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	17.07.2012 to 27.08.2012	Mild
8.	7315	PARTHASARATHY	64/M	Itching, erythema, lichenification, pustules, oozing, present	23.07.2012 to 30.08.2012	Marked
9.	7320	USHA	38/F	Itching, erythema, lichenification, pustules, oozing, varicose vein present	23.07.2012 to 04.09.2012	Moderate
10.	7498	VIJAYAKUMAR	47/M	Itching, erythema, lichenification, varicose vein present	24.07.2012 to 11.09.2012	Marked

CLINICAL STUDY ON *AIVAELI SAMOOLA CHOORANAM* FOR KARAPPAN (O.P)

Sl.No.	O.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
11.	887	CHANDRAN	63/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	06.08.2012 to 20.09.2012	Marked
12.	897	BHUWANESWARI	37/F	Itching, erythema, lichenification, pustules, pustule, present	06.08.2012 to 18.09.2012	Poor
13.	912	GAYATHRI	26/F	Itching, erythema, lichenification, pustules,vesicle present	06.08.2012 to 10.08.2012	Marked
14.	2539	KANTHA	45/F	Itching, erythema, lichenification, pustules, oozing, varicose vein present	13.08.2012 to 01.10.2012	Marked
15.	969	THULASIRAMAN	48/F	Itching, erythema, lichenification, pustules, oozing, present	06.08.2012 to 22.09.2012	Marked
16.	4472	SAKTHIKANI	47/F	Itching, erythema, lichenification, pustules, oozing, present	22.08.2012 to 10.09.2012	Marked
17.	1001	ROHINI	48/F	Itching, erythema, lichenification, pustules, oozing, present	06.08.2012 to 23.09.2012	Moderate
18.	8922	VAANI	45/F	Itching, erythema, lichenification, pustules, vesicles present	10.09.2012 to 30.10.2012	Marked
19.	6618	DURAIVELU	55/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	12.10.2012 to 29.11.2012	Marked
20.	6851	DEVI	40/F	Itching, erythema, lichenification,Presentesen	13.10.2012 to 01.12.2012	Mild

21.	6886	PAZHANI	45/M	Itching, erythema, lichenification, pustules, vesicles present	13.10.2012 to 30.11.2012	Marked
22.	7780	KAMALAKANNAN	34/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	17.10.2012 to 27.11.2012	Moderate
23.	7778	SIVAKUMAR	40/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	17.10.2012 to 03.12.2012	Marked
24.	7711	KANNAN	40/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	17.10.2012 to 05.12.2012	Marked
25.	1293	RAJESWARI	55/F	Itching, erythema, lichenification, pustules, vesicles present	05.11.2012 to 20.12.2012	Marked
26.	1517	CHELLAMAL	45/F	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	06.11.2012 to 22.12.2012	Marked
27.	1671	KALAIARASI	42/F	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	06.11.2012 to 24.12.2012	Poor
28.	1758	KARTHIK	28/M	Itching, erythema, lichenification, pustules, vesicles present	07.11.2012 to 20.12.2012	Marked
29.	496	RAVI	42/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	01.11.2012 to 18.12.2012	Moderate
30.	1272	RAJAN	58/M	Itching, erythema, lichenification, pustules, vesicles present	05.11.2012 to 19.12.2012	Marked

31.	1557	JAYAKUMAR	30/M	Itching, erythema, lichenification, pustules, vesicles present	06.11.2012 to 16.12.2012	Poor
32.	1805	SELVAM	35/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	07.11.2012 to 20.12.2012	Marked
33.	8006	TAMIZHARASU	38/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	18.10.2012 to 11.11.2013	Moderate
34.	1865	PURUSOTHAMAN	37/M	Itching, erythema, lichenification, pustules, vesicles present	07.11.2012 to 25.12.2012	Moderate
35.	2083	PONVARANGAM	36/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	08.11.2012 to 24.12.2012	Marked
36.	2260	SATHYAMOORTHY	32/M	Itching, erythema, lichenification, pustules, vesicles present	09.11.2012 to 27.12.2012	Marked
37.	2287	NAVEEN	34/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	09.11.2012 to 22.12.2012	Marked
38.	1890	KALAIVANI	32/F	Itching, erythema, lichenification, pustules, vesicles present	07.11.2012 to 23.12.2012	Marked
39.	1892	REVATHI	32/F	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	10.11.2012 to 26.12.2012	Moderate
40.	1894	VASUDEVAN	24/M	Itching, erythema, lichenification, pustules, vesicles present	07.11.2012 to 29.12.2012	Marked

CLINICAL STUDY ON *AIVAELI SAMOOLA CHOORANAM* FOR KARAPPAN (I.P)

Sl.No.	I.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
1.	1089/7184	FRANCIS	60/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	23.07.2012 to 27.08.2012	Marked
2.	1447/8001	ARUMUGAM	67/M	Itching, erythema, lichenification, pustules, oozing, varicose vein present	06.09.2012 to 19.10.2012	Marked
3.	1152/8998	VIJAYARANI	50/F	Itching, erythema, lichenification, pustules, vesicles present	30.07.2012 to 13.08.202	Marked
4.	1216/924	MAHESWARI	46/F	Itching, erythema, lichenification, pustules, vesicles present	06.08.2012 to 12.09.2012	Marked
5.	1326/4614	USEN	37/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	22.08.2012 to 23.09.2012	Marked
6.	8/9848	KARNAN	43/M	Itching, erythema, lichenification, pustules, vesicles present	14.09.2012 to 26.10.2012	Marked
7.	163/4326	THULASI	38/F	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	03.10.2012 to 09.11.2012	Marked
8.	1236/1516	MAREEN	58/M	Itching, erythema, lichenification, pustules, vesicles present	08.08.2012 to 10.09.2012	Marked
9.	1342/5169	BHASEER	51/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	25.08.2012 to 10.10.2012	Marked
10.	1363/5792	KUMAR	40/M	Itching, erythema, lichenification, pustules, vesicles pain, ulcer present	28.08.2012 to 10.10.2012	Marked

Sl. No.	O.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														B.S Mg/dl		URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)				BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT			Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr			BT	AT						
1.	7439	SHANTHAM	55/F	9400	57	38	5	9300	58	39	3	13	33	10	30	12	12.4	113	109	NIL	NIL	OPC	NIL	NIL	NIL
2.	099	KAVITHA	37/F	9300	56	38	6	9400	57	39	4	14	34	10	18	10	10.2	96	92	NIL	NIL	NIL	NIL	NIL	NIL
3.	782	RADHABAI	69/F	9000	55	40	5	9100	55	12	3	16	37	10	18	11	11	115	101	NIL	NIL	FPC	NIL	NIL	NIL
4.	3189	SANGEETHA	28/F	9200	56	32	12	9200	59	35	6	20	42	10	22	11.2	11.4	92	96	NIL	NIL	FPC	NIL	NIL	FPC
5.	3684	ANANTH	42/M	8700	58	36	6	9800	60	36	4	18	40	14	28	12	13	109	87	NIL	NIL	FPC	NIL	NIL	FPC
6.	5661	SUNDHARESAN	55/M	8800	56	38	6	9000	56	40	4	18	38	12	26	14	14.2	110	100	NIL	NIL	NIL	NIL	NIL	NIL
7.	5819	SAKTHI	35/M	9200	58	35	7	9400	57	40	3	5	11	5	10	14.6	15	99	96	NIL	NIL	FPC	NIL	NIL	NIL
8.	7315	PARTHASARATHY	64/M	8900	60	35	5	9000	59	38	3	7	17	6	14	7.2	8.8	89	94	NIL	NIL	FPC	NIL	NIL	FPC
9.	7320	USHA	38/F	9200	59	33	8	9200	60	35	5	13	28	8	17	9.8	10.1	102	99	NIL	NIL	FPC	NIL	NIL	FBC
10.	7498	VIJAYAKUMAR	47/M	8800	57	34	9	9000	60	35	5	16	30	10	22	13.5	14	112	108	NIL	NIL	NIL	NIL	NIL	NIL
11.	887	CHANDRAN	63/M	9200	59	35	6	9900	60	36	4	26	48	12	35	12	13	108	89	NIL	NIL	NIL	NIL	NIL	NIL
12.	897	BHUWANESWARI	37/F	10000	66	28	6	9900	62	34	4	33	63	18	38	12	12.8	83	80	NIL	NIL	FPC	NIL	NIL	NIL
13.	912	GAYATHRI	26/F	9300	55	39	6	9400	58	39	3	12	39	8	20	12	12.5	83	90	NIL	NIL	NIL	NIL	NIL	NIL
14.	2539	KANTHA	45/F	9900	60	36	4	9900	60	37	3	12	33	9	18	12.6	13.2	101	98	NIL	NIL	FPC	NIL	NIL	NIL
15.	969	THULASIRAMAN	48/F	9700	59	38	3	9800	60	37	3	3	8	4	8	12.8	13	106	102	NIL	NIL	NIL	NIL	NIL	NIL
16.	4472	SAKTHIKANI	47/F	9400	55	41	4	9500	56	41	3	18	34	10	18	9.8	10.2	118	106	NIL	NIL	FPC	NIL	NIL	FPC
17.	1001	ROHINI	48/F	9200	62	30	8	9400	66	30	4	14	30	7	15	10.2	11	95	90	NIL	NIL	NIL	NIL	NIL	NIL
18.	8922	VAANI	45/F	9000	52	31	7	9300	54	32	4	16	40	12	36	9.6	10.4	110	102	NIL	NIL	FPC	NIL	NIL	NIL
19.	6618	DURAIVELU	55/M	9700	55	37	8	9800	59	38	3	12	26	6	14	11.8	12.2	118	111	NIL	NIL	NIL	NIL	NIL	NIL
20.	6851	DEVI	40/F	9800	53	40	7	9900	56	39	5	19	28	11	22	10	10.8	98	94	NIL	NIL	NIL	NIL	NIL	NIL

Sl. No.	O.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT																URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		B.S gm/dl		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr										
21.	6886	PAZHANI	45/M	9800	53	41	6	9900	54	43	3	12	26	6	14	13	13.5	110	106	NIL	NIL	NIL	NIL	NIL	NIL
22.	7780	KAMALAKANNAN	34/M	7600	58	37	5	7800	58	39	3	16	32	7	14	12.4	13	104	98	NIL	NIL	FPC	NIL	NIL	FPC
23.	7778	SIVAKUMAR	40/M	8900	61	31	8	9100	63	33	4	14	28	8	16	14	14.8	115	101	NIL	NIL	NIL	NIL	NIL	NIL
24.	7711	KANNAN	40/M	9100	63	31	6	9300	64	33	3	8	16	4	8	12	12.8	112	102	NIL	NIL	FPC	NIL	NIL	FPC
25.	1293	RAJESWARI	55/F	9000	54	38	8	9200	57	39	4	20	45	12	18	11.8	12.4	133	109	NIL	NIL	FPC	NIL	NIL	NIL
26.	1517	CHELLAMAL	45/F	8900	53	40	7	9000	56	41	3	27	55	20	40	13	13.5	80	94	NIL	NIL	FPC	NIL	NIL	FPC
27.	1671	KALAIARASI	42/F	9000	51	43	6	9200	52	44	4	20	44	14	26	11.5	12.2	88	90	NIL	NIL	NIL	NIL	NIL	NIL
28.	1758	KARTHIK	28/M	7900	55	37	8	8100	57	38	5	22	46	10	18	11.5	12	96	94	NIL	NIL	NIL	NIL	NIL	NIL
29.	496	RAVI	42/M	7900	61	31	8	9800	62	34	4	22	44	12	18	13	13.5	82	84	NIL	NIL	FPC	NIL	NIL	FPC
30.	1272	RAJAN	58/M	8100	59	34	7	8000	61	35	4	16	32	8	16	12	13	102	100	NIL	NIL	NIL	NIL	NIL	NIL
31.	1557	JAYAKUMAR	30/M	9200	58	35	7	9100	60	36	4	24	38	12	24	10	11	106	98	NIL	NIL	NIL	NIL	NIL	NIL
32.	1805	SELVAM	35/M	9500	61	33	6	9600	62	35	3	12	26	8	14	13	14	92	88	NIL	NIL	NIL	NIL	NIL	NIL
33.	8006	TAMIZHARASU	38/M	9200	57	36	7	9400	59	37	4	14	28	6	12	12	15	102	106	NIL	NIL	FPC	NIL	NIL	FPC
34.	1865	PURUSOTHAMAN	36/M	9700	55	37	8	9800	57	44	4	24	42	13	20	10	12	98	96	NIL	NIL	NIL	NIL	NIL	NIL
35.	2083	POVARANGAM	36/M	9300	53	40	7	9400	55	42	3	22	44	12	18	12	14	110	104	NIL	NIL	NIL	NIL	NIL	NIL
36.	2260	SATHYAMOORTHY	32/M	9500	54	38	8	9600	58	38	4	12	28	9	14	13	14	98	94	NIL	NIL	NIL	NIL	NIL	NIL
37.	2287	NAVEEN	34/M	9900	61	33	6	9800	61	36	3	14	26	8	12	12	14	102	104	NIL	NIL	FPC	NIL	NIL	FPC
38.	1890	KALAIVANI	32/F	7600	59	34	7	7900	60	37	3	22	44	14	22	10	10.5	106	98	NIL	NIL	NIL	NIL	NIL	NIL
39.	1892	REVATHI	32/F	7500	58	35	7	7700	60	36	4	16	28	7	15	9.5	10	98	92	NIL	NIL	FPC	NIL	NIL	FPC
40.	1894	VASUDEVAN	24/M	8900	55	37	8	9100	57	44	4	14	28	8	16	12	12.5	102	98	NIL	NIL	FPC	NIL	NIL	FPC

Sl. No.	I.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT																URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		B.S gm/dl		BT			AT		
				TC CU/ mm	DC			TC CU/mm	DC			BT		AT		BT	AT	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr											
1.	1089/7184	FRANCIS	60/M	9300	62	32	6	9400	63	33	4	12	24	6	10	11	11.5	115	110	NIL	NIL	NIL	NIL	NIL	NIL
2.	1447/8001	ARUMUGAM	67/M	9700	61	32	7	9800	63	33	5	15	28	10	14	13	14	120	108	NIL	NIL	FPC	NIL	NIL	NIL
3.	1152/8998	VIJAYARANI	50/F	9800	53	41	6	9900	55	41	4	14	28	8	14	10	11	98	92	NIL	NIL	PC	NIL	NIL	FPC
4.	1216/924	MAHESWARI	46/F	8800	55	38	7	8900	59	38	3	15	30	7	14	9.8	10	101	98	NIL	NIL	NIL	NIL	NIL	NIL
5.	1326/4614	USEN	37/M	9700	53	40	7	9800	55	41	4	12	24	6	12	12	12.5	111	99	NIL	NIL	FPC	NIL	NIL	NIL
6.	8/9848	KARNAN	43/M	9500	62	32	6	9600	63	33	4	10	28	5	10	14	14	110	102	NIL	NIL	FPC	NIL	NIL	FPC
7.	163/4326	THULASI	38/M	9300	54	38	8	9400	57	38	5	12	32	8	16	11	11.5	98	96	NIL	NIL	NIL	NIL	NIL	NIL
8.	1236/1516	MAREEN	58/M	9500	55	38	7	9600	59	38	3	16	34	9	16	10.5	11	102	98	NIL	NIL	FPC	NIL	NIL	FPC
9.	1342/5169	BHASEER	51/M	9200	58	36	6	9400	59	38	3	2	26	4	8	10	10.5	104	100	NIL	NIL	NIL	NIL	NIL	NIL
10	1363/5792	KUMAR	40/M	9100	61	32	7	9200	63	33	5	14	22	6	12	12.4	13	110	98	NIL	NIL	NIL	NIL	NIL	NIL

ECZEMA AREA SEVERITY INDEX SCORE

S.NO	O.P NO	NAME	AGE/SEX	EASI SCORE	
				BT	AT
1.	7439	SHANTHAM	55/F	3.8	0.8
2.	099	KAVITHA	37/F	4.6	1.8
3.	782	RADHA BAI	69/F	4	0.2
4.	3189	SANGEETHA	28/F	10.8	1.6
5.	3684	ANANDH	42/M	3.6	0.2
6.	5661	SUNDHARESAN	55/M	0.6	0.2
7.	5819	SAKTHI	35/M	7.2	2.8
8.	7315	PARTHASARATHY	64/M	5.2	0.4
9.	7320	USHA	38/F	3.2	0.8
10.	7498	VIJAYAKUMAR	47/M	0.8	0.2

ECZEMA AREA SEVERITY INDEX SCORE

S.NO	O.P NO	NAME	AGE/SEX	EASI SCORE	
				BT	AT
11.	887	CHANDRAN	63/M	4.0	1.0
12.	897	BHUWANESWARI	37/F	2.8	1.8
13.	912	GAYATHRI	26/F	4.2	0.4
14.	2539	KANTHA	45/F	12	1.8
15.	969	THULASIRAMAN	48/F	5.4	1
16.	4472	SAKTHIKANI	47/F	15	3
17.	1001	ROHINI	48/F	10	1.8
18.	8922	VAANI	45/F	4	0.8
19.	6618	DURAIVELU	55/M	8	1.2
20.	6851	DEVI	40/F	6	2.8

ECZEMA AREA SEVERITY INDEX SCORE

S.NO	O.P NO	NAME	AGE/SEX	EASI SCORE	
				BT	AT
21.	6886	PAZHANI	45/M	3	0.2
22.	7780	KAMALAKANNAN	34/M	6	0.4
23.	7778	SIVAKUMAR	40/M	8	1.4
24.	7711	KANNAN	40/M	15.4	3
25.	1293	RAJESWARI	55/F	10	1.2
26.	1517	CHELLAMAL	45/F	14	1.6
27.	1671	KALAIARASI	42/F	6	3.4
28.	1758	KARTHIK	28/M	14	2
29.	496	RAVI	42/M	4	0.1
30.	1272	RAJAN	58/M	12	2.2

ECZEMA AREA SEVERITY INDEX SCORE

S.NO	O.P NO	NAME	AGE/SEX	EASI SCORE	
				BT	AT
31.	1557	JAYAKUMAR	30/M	8	1.6
32.	1805	SELVAM	35/M	18	3
33.	8006	TAMIZHARASU	38/M	18	3.8
34.	1865	PURUSOTHAMAN	37/M	10.5	2.6
35.	2083	PONVARANGAM	36/M	10	2.2
36.	2260	SATHYAMOORTHY	32/M	8	2.2
37.	2287	NAVEEN	34/M	3	0.2
38.	1890	KALAIVANI	32/F	6	1.4
39.	1892	REVATHI	32/F	5.8	0.6
40.	1894	VASUDEVAN	24/M	5	2.6

ECZEMA AREA SEVERITY INDEX SCORE

S.NO	I.P NO	NAME	AGE/SEX	EASI SCORE	
				BT	AT
1	1089/7184	FRANCIS	60/M	12	2.4
2.	1447/8001	ARUMUGAM	67/M	4	0.6
3.	1152/8998	VIJAYARANI	50/F	6.4	1.4
4.	1216/924	MAHESWARI	46/F	7.4	2.0
5.	1326/4614	USEN	37/M	4	0.8
6.	8/9848	KARNAN	43/M	14	2.8
7.	163/4326	THULASI	38/F	10.2	2.2
8.	1236/1516	MAREEN	58/M	9.2	1.8
9.	1342/5169	BHASEER	51/M	11.4	2.4
10.	1363/5792	KUMAR	40/M	9.6	1.4

5. RESULTS AND DISCUSSION

Many types of studies had been focused on *Aivaeli samoola Chooranam* to demonstrate its superiority and therapeutic efficacy. Explorations like literary collections, pharmacognostic study, physicochemical and phyto chemical analysis, toxicological study, pharmacological study and clinical study are carried to sustain the aim and objective of the study

Literary review of *Aivaeli samoola chooranam* shows that it has bitter in taste.

Siddha have unique methodology of selecting a drug of choice for a disease based on humoral pathology of the disease and *suvai* of the drug. *Suvai* based medicine selection could give better result as at is in successful practice from ancient days.

கைப்பு சுவையின் பண்பு

குடற்புழு குட்டம் கொடிய நஞ்சு

வாய்நீ ரூறல் அழற்சியும் தணிக்கும்

-மருத்துவ தனிப்பாடல்-

As per literature, Bitter taste has the property to reduce the skin manifestations. Because of its bitter taste, it has a specialty in treating skin disease like *Karappan.*

STANDARDIZATION OF PLANT DRUG

Pharmacognostic Study of *Aivaeli samoola chooranam*:

Macroscopic

Perennial, monoecious herb climbing by bifid tendrils.

Stem up to6m long. Young stems spotted with darker green.

Leaves alternate, simple; stipules absent; petiole 2-10cm long; blade broadlyovate, palmately 5 lobed up to 14cm x 15cm;base cordate; lobes narrowly elliptical, margin sinuatedentate.

Inflorescence an axillary cluster with usually both male and female flowers in same axil.

Flowers unisexual,regular,5-merous corolla white to greenish-yellow;male flowers pedicellate,with 3 free stamens;female flowers subsessile,with inferior ,1 celled ovary,stigma 3-lobed.

Fruit a subglobose, indehiscent berry 1.5-12.5 cm in diameter, solitary or clustered, red with silvery white longitudinal stripes.

Microscopic

T. S of Leaf

Leaf is dorsiventral with prominent aboxical part of the midrib bifacial lamina (Fig 1.1). The midrib consists of small, blung adaxial cone and widet thick somewhat labed abaxial part. The midrib is 440mm thick and 400mm broad. The epidermal layer of the midrib consists of small, squorish, thin walled cells within the adaxial cone occurs small, compact, mass of collenchimpa cells. The ground tissue is homogeneous parenchypmatous, thin walled, angular & compact (Fig 1.2). The vascular strand is single, small and bowl shaped. It consists of a cluster of wide, angular, thick walled refen and a thin layer of phloem on the lower part of the xylem strand (Fig 1.3).

Lamina:

The Lamina is 100mm thick. The adaxial epidermis includes fairly thick rectangular cells with thin cuticle. The aboxial epidermis is also fairly thick with rectangular thin walled cells. The Palirade tissue consists of a single band of thick, cylindrical, less compact cells. The spongy mesophyll consists of 3 or 4 layers of spherical or lobed cells which form narrow air chambers (Fig 1.4)

Root

Both thin and thick roots are studied. The thin root (Fig 2.1) and thick root (Fig 3.1) are basically similar in structure. The root consists of outer narrow, less district periderm layer and thick parenchymatous cortex. Fig (2.1 & 1 & 2, 3.1).

The vascular cylinder is unusual (anamelous) in structure. In thin root there are 4 radiating fan shaped wings of vessel elements with broad vascular rays inbetween the radial wings. (Fig 2.1) In case of thick root the xylem elements occur in about 6 radial wings with wide parenchumatous rays in between the wing (Fig 3.1) Instead of having solid, dense xylem cylinder in this case xylem elements are broken in radiating wings by wide parenchymatous rays. So, this feature is considered to be anamolous structure. The vessel elements are very wide, circular and fairly thick walled, within the vessel elements

are seen thin vesicles called thyloses, which are broken and collapsed (Fig 2.2 & 2.3, 3.2). The vessel elements are ensheathed by thin layer of fibers. Phloem occurs at the accouter ends of radial segments of xylem. The vessel elements in the centre are narrow, those towards the periphery are wider, The outer vessel elements are 200-250µm wide.

Flowers

The flowers are unisexual and the plants are monecious Male and Female flowers occur in the axils of same plant. The petals and sepals are 5 lobed, stamens three 1 stamens has one celled another, the other two have 2 celled anther. The stamers are attached on the throat of the sepals (Fig 4.1). The another wall is 2 layered and thin walled (Fig 4.2). The Pollen Grains are circular with thick and smonth exicts (Fig 4.2 & 3)

The Pollen Grains are 50µm in diameter.

Female Flower

The Ovary is ovoid. It is tricarpellary, syncarpous with parietal Placentation. Ovules are many, the ovary develops into ovoid, pulpy many seeded berry. The ovule is cylindrical with elongated cylindrical embryo (Fig 5 & 6.1). The pericarp is 400µm thick. It consists of thick walled epidermal layer and the mesocarp having outer small, thick walled ground cells & Inner Larger, thin walled parenchyma cells. Vasuclar bundles are seen in the thin walled parenchyma zone. The vascular bundles are bicollatoral with central xylem and phloem on outer & Inner parts of xylem strand (Fig 6.3).

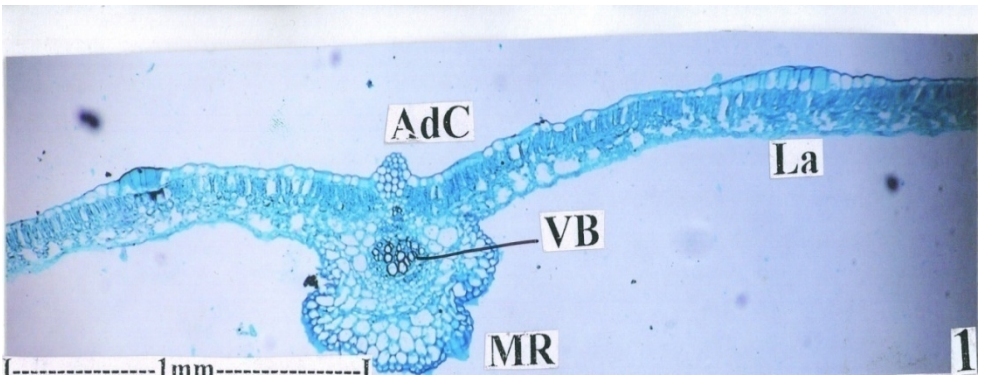


Fig: 1.1- T.S of leaf through midrib & lamina

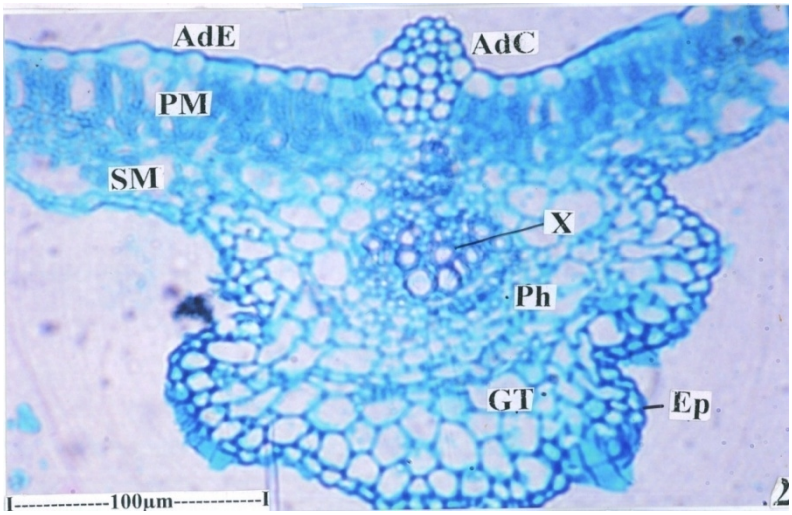


Fig: 1.2- T.S of midrib-enlarged

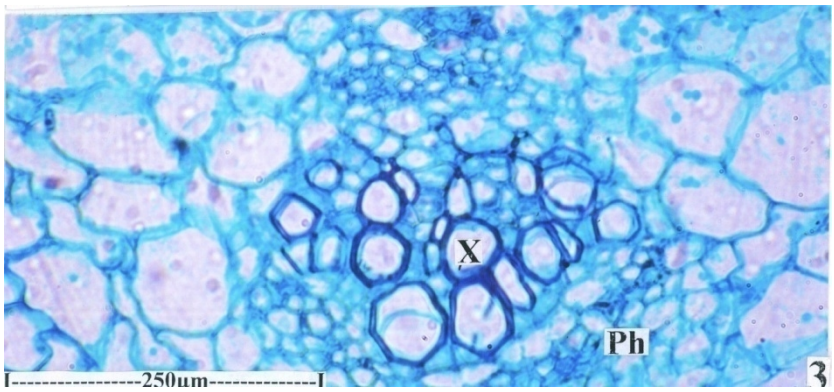


Fig: 1.3-Vascular strand of the midrid enlarged

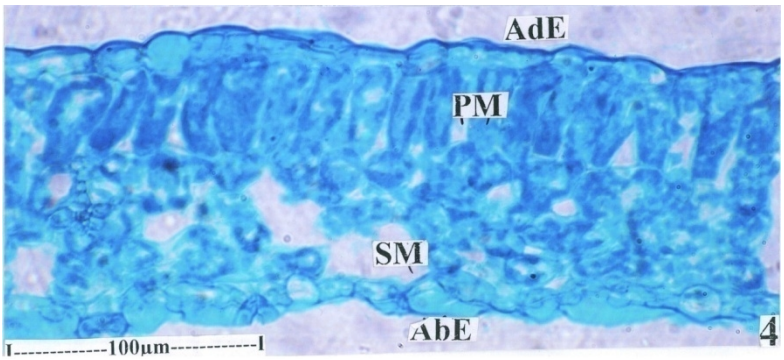


Fig: 1.4- T.S of lamina

Abe	-	Abaxial epidermis,	Adc	-	Adaxial core
Ep	-	Epidermis,	GT	-	Ground tissue
La	-	Lamina,	MR	-	Midrib
Ph	-	Phloem,	PM	-	Palisade mesophyll
SM	-	Sponcy mesophyll,	VB	-	Vascular bundle,
X	-	Xylem			

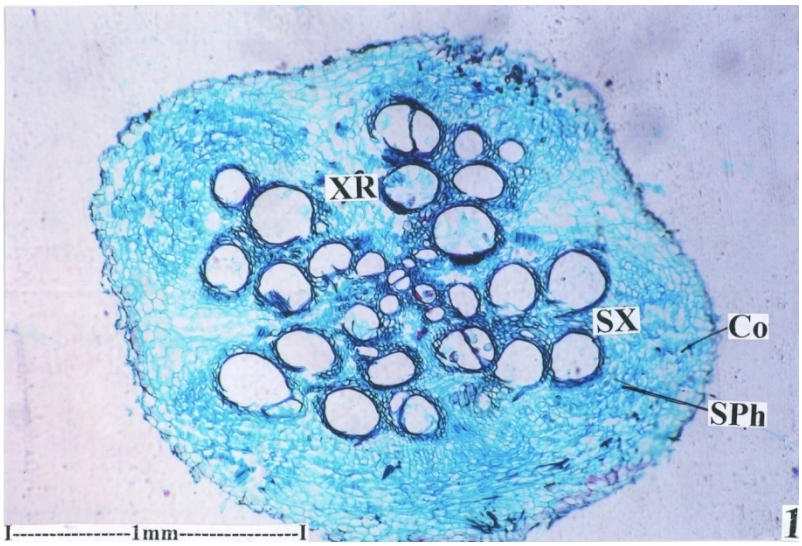


Fig: 2.1 T.S of thin root-Entire view

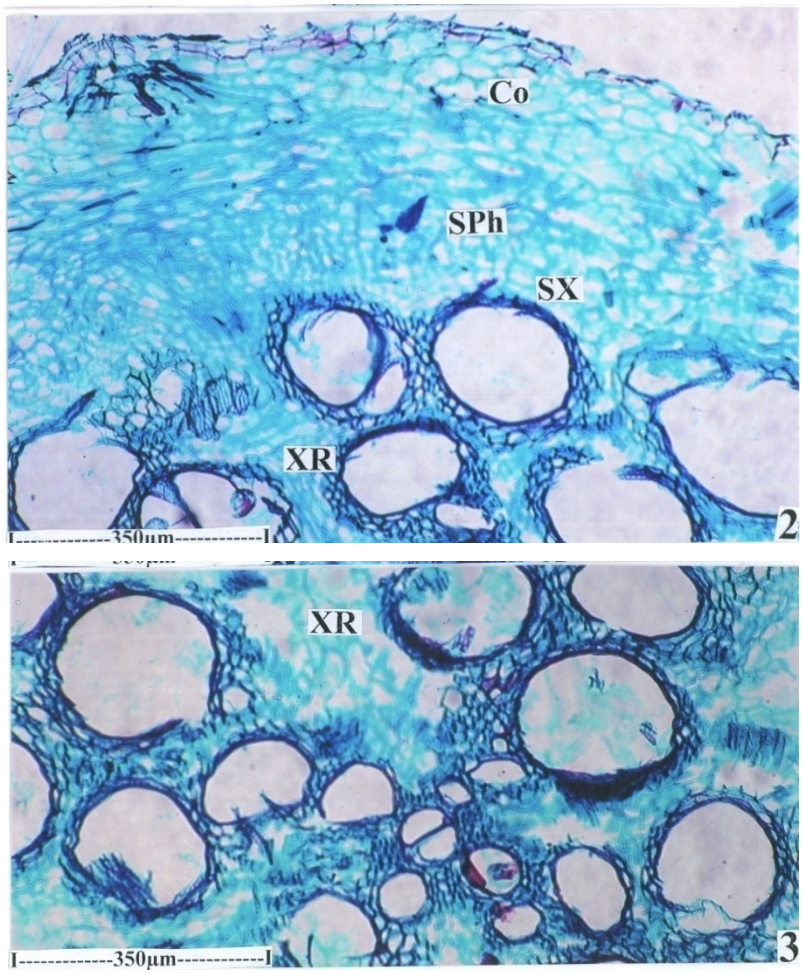


Fig: 2.2 & 2.3-Vascular cylinder showing radiating segments

Co	-	cortex	Sph	-	Secondary phloem
SX	-	Secondary xylem	XR	-	Xylem ray

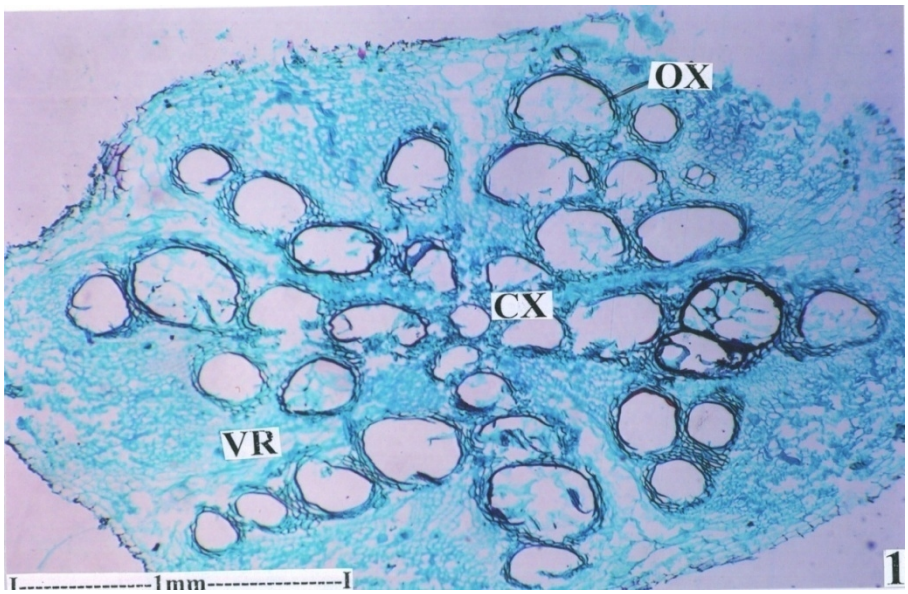


Fig: 3.1 T.S of thick root-Entire view

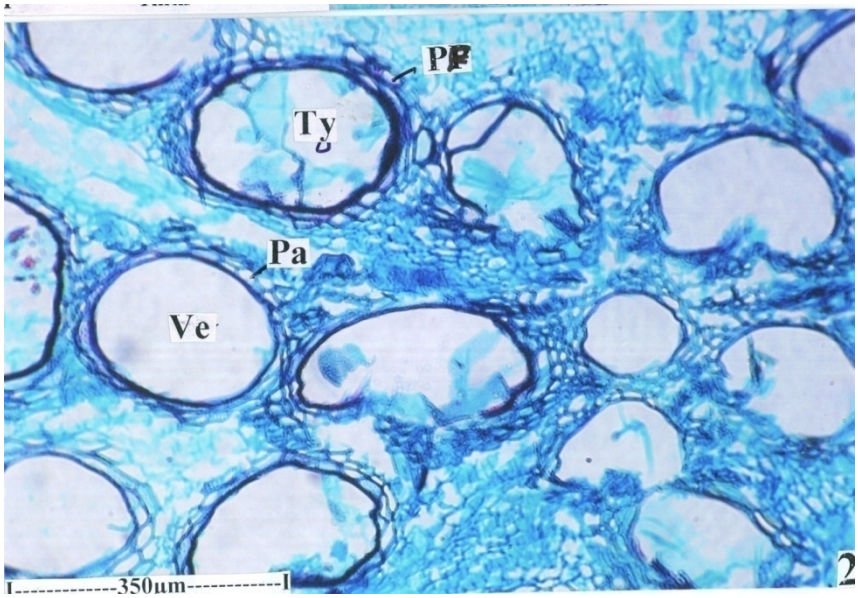


Fig: 3.2-Vessel elements with broken Tyloses

Cx	-	central Xylem	Ox	-	Outer xylem
Pa	-	Parenchyma	PF	-	Paratrachial fibers
VR	-	Vascular ray	Ty	-	Tyloses

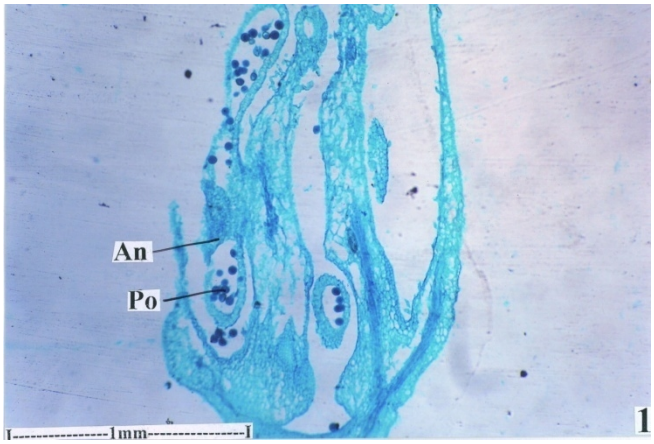


Fig: 4.1-L.S of Male flower

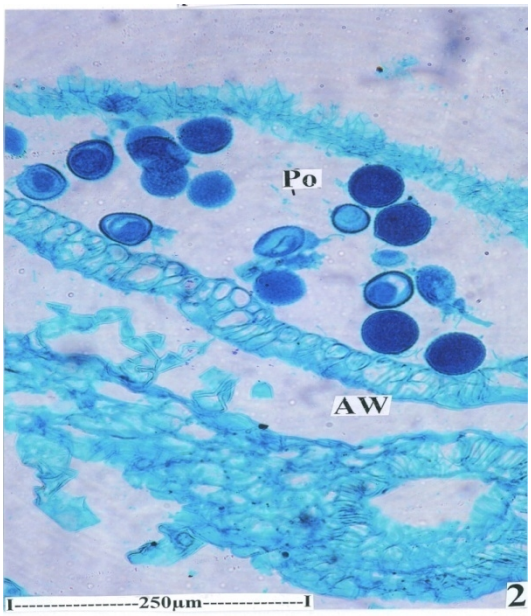


Fig: 4.2 -T.S of Anther-Enlarged

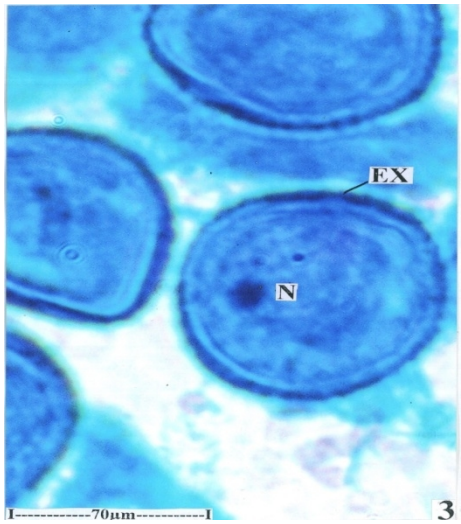


Fig: 4.3-Pollen grarins enlarged

An	-	Anther	AW	-	Anti-clinal wall
N	-	Nucleus	Po	-	Pollen

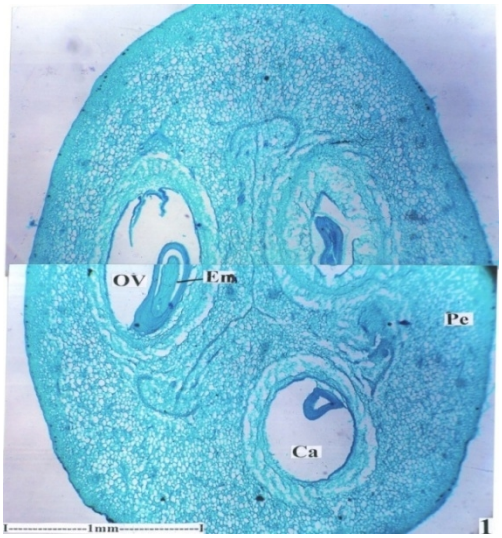


Fig: 5.1 T.S of Fruit

Ca	-	carpel,	Em	-	Embryo
Pe	-	Pericarp,	OV	-	Ovule

Fig: 6.1 L.S of seed with embryo

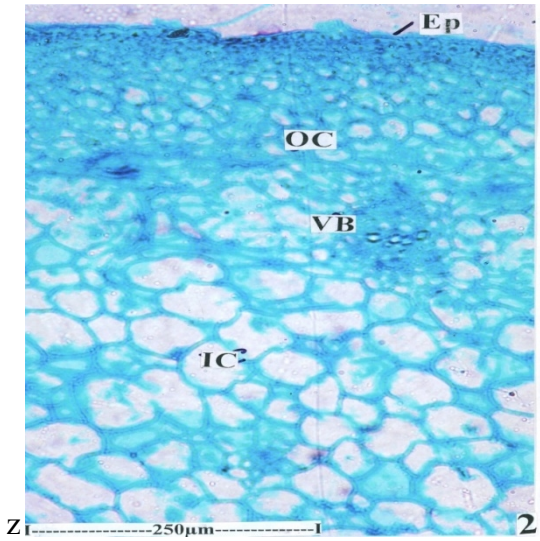


Fig: 6.2-Pericarp of the fruit

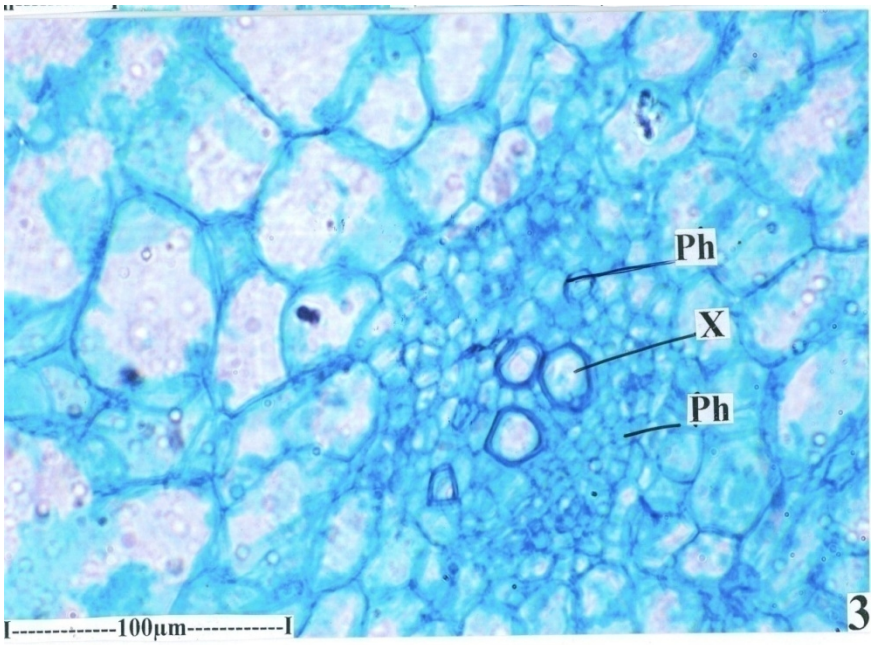


Fig: 6.3-Vascular bundle of the pericarp

Em	-	embryo,	OV	-	Ovule
Ph	-	Phloem,	X	-	Xylem
Ep	-	Epidermis,	IC	-	Inner cortex
OC	-	Outer cortex,	VB	-	Vascular bundle

Pharmacognostic study shows microscopical structures of the herb *Diplocyclos palmatus*. It is used to recognize the plants in fresh and dried samples and to identify the adulteration of the drug.

ORGANOLEPTIC CHARACTERS

The following organoleptic characters are noted in *Aivaeli samoola chooranam*

Table No 5

Appearance	**Powder**
Colour	light brown
Odour	Odourless
Taste	Bitter
Texture	Fine

PHYSICO-CHEMICAL INVESTIGATIONS OF DRUG

S.No	**Parameter**	**Mean Value**
1.	Loss on Drying at 105°C	8.573 %
2.	Total Ash	12.572 %
3.	Acid insoluble Ash	1.075 %
4.	Water Soluble Extractive	26.0 %
5.	Alcohol Soluble Extractive	14.85 %
6.	Particle size	Completely passes through sieve no.44
7.	Ph	6.2

- Loss on drying (LOD) gives the total of volatile content and moisture present in the drug. The stability of a drug and its shelf-life is dependent on moisture –content. Moisture increases can adversely affect the active ingredient. Low moisture content, drug could get maximum stability and better shelf life.
- Total ash value measures the total inorganic content (ammonium, potassium, calcium, chloride, iron, etc.) present in the drug.
- Acid insoluble ash value of a drug says the amount of siliceous matter present in the plant. Lower the acid insoluble value better will be the drug quality. (1.075%)

- Water extractive and ethanol extractive values give the percentage of soluble matters present in the drug. Suitable solvent could be selected based on the extractive value. Also it gives the percentage of drug which will interrelate with the metabolism reactions.
- pH value indicates the nature of the drug whether it is alkaline or acidic. pH value 0 to less than 7 shows the drug is acidic in nature.

TLC Estimation of Aivaeli samoola chooranam

After spray with visualizing agent

Sl.No	After Dipping in Vanillin-Sulphuric acid	
	Rf value	**Colour of the spot**
1	0.19	Bluish grey
2	0.27	Bluish grey
3	0.53	Violet
4	0.66	Violet
5	0.73	Greenish yellow
6	0.81	Greyish blue
7	0.97	Violet

Thin Layer Chromotography is used for precise identification and adulterant of the plant drug. Identification was effected by study of spots of identical Rf value and about equal magnitude obtained, respectively, with an unknown and a reference sample chromatographed on the same plate. The visual similarity of the size and intensity of the spots supported in semi-quantitative estimation of plant.

Standardization of drugs aids in confirmation of identity and determination of quality, effectiveness of *Diplocyclos palmatus.*

PHYTO CHEMICAL EVALUATION OF *AIVAELI SAMOOLA CHOORANAM*

The qualitative analysis on phyto chemical substance on *Aivaeli* Shows presence of **Alkaloids, Flavonoids**, **Triterpenes**,, **Steroids, Saponins**, and **Proteins.**

1.	Alkaloids	+ ve
2.	Triterpenes	+ ve
3.	Flavonoids	+ ve
4.	Saponin	+ ve
5.	Steroids	+ ve
6.	Protein	+ ve
7.	Anthraquinones	- ve
8.	Acid	- ve
9.	Coumarin	- ve

INTERPRETATION

Saponin have Fungitoxic activity (David R.Gang 2011) and terpenes have anti-inflammatory activity (Iris F.Benzie*et al* -2011). These two phytochemical activity is essential for a drug to manage Eczema. As these are present in the *Aiveli samoola chooranam*, its indication to *karappan* is justified phytochemically.

PRELIMINARY CHEMICAL ANALYSIS OF AIVAELI SAMOOLA CHOORANAM

S.NO	TEST FOR CHEMICALS	RESULT
1.	Reducing sugar	Absent
2.	Starch	Absent
3.	Protein	Absent
4.	Amino acid	Present
5.	Albumin	Absent
6.	Phosphate	Present
7.	Sulphate	Present
8.	Chloride	Present
9.	Iron	Present
10.	Calcium	Present
11.	Sodium	Absent
12.	Potassium	Absent
13.	Zinc	Present
14.	Magnesium	Present
15.	Alkaloids	Present
16.	Tannic acid	Present

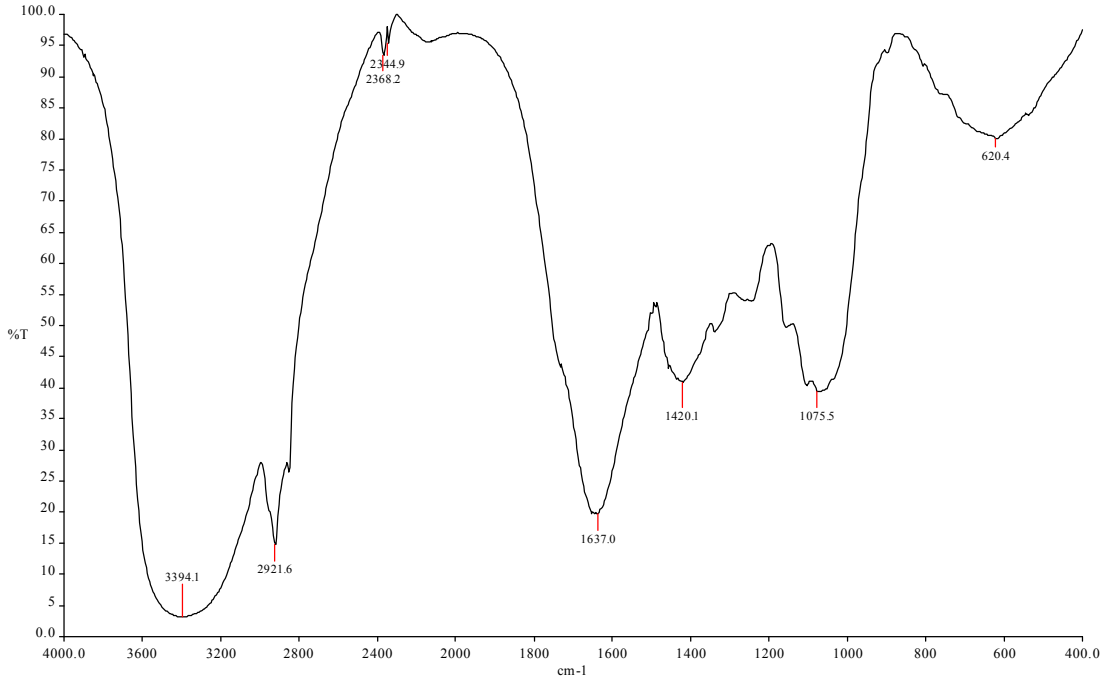
INTERPRETATION

From the preliminary chemical analysis ,we came to know that the trial drug have Amino acid, Phosphate, Sulphate, Chloride, Iron, Calcium, Zinc, Magnesium, Alkaloids, Tannic acid.

Zinc has potent wound healing activity (Sathyanarayana). Zinc in *Aiveli samoola chooranam* might be the reason for its action in healing ulcers seen in Eczema.

Elemental Analysis of Drug:

Fourier Transforms Infrared Spectroscopy (FT-IR):



FT-IR is the acronym for Fourier Transform Infrared Spectroscopy. FT-IR is a spectroscopic technique that utilizes lower energy radiation to induce vibration and rational excitation of atoms and groups of atoms within molecules. Because of the variety of symmetry of atomic groups and their differences in atomic masses and electronic structure the absorption patterns for a specific species will be unique, which allows for their identification. Infrared spectroscopic technique used to identify the functional groups in organic and inorganic compounds.

Principle

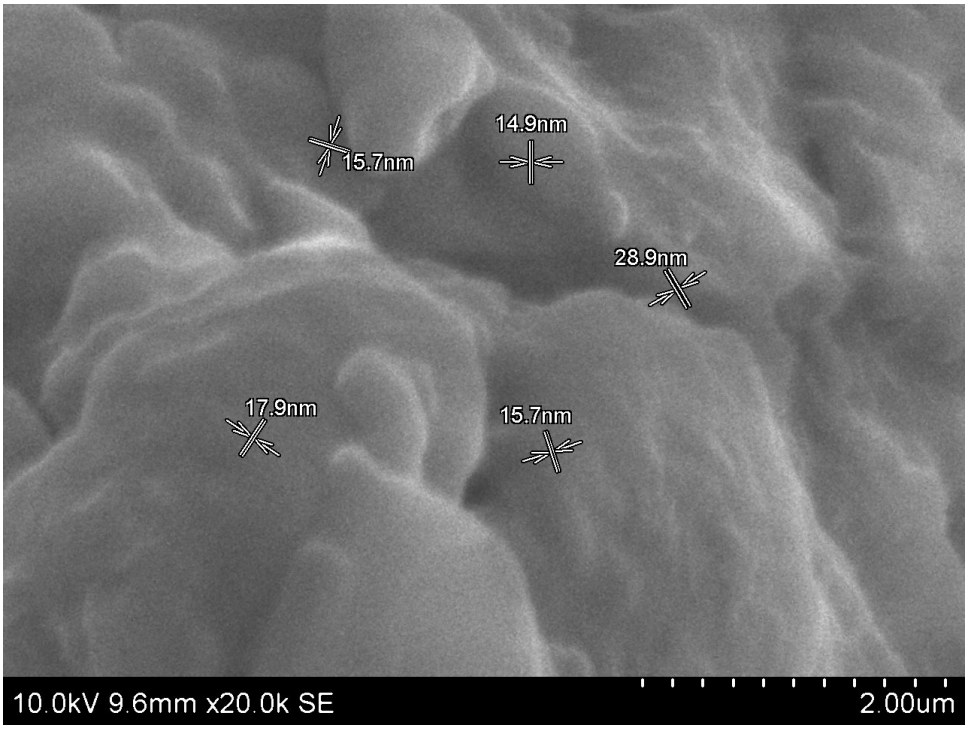
IR interacts with the sample and the bonds between atoms in the molecule stretch and bend, absorbing infrared energy and creating the infrared spectrum. It is of two types bending and stretching.

FT-IR is a very useful tool in the detection of the functional groups of bio molecules, thus aiding in their structural elucidation, thereby confirming the presence of active molecules responsible for the therapeutic activity of *Siddha* drugs.

Aivaeli samoola chooranam have following functional groups.

PEAK VALUES	FUNCTIONAL GROUPS
3394.1	Phenols and Alcohols
2921.6	Alkanes
2368.2	Amine
2344.9	Amine
1637.0	Alkens
1420.1	Aromatic groups
1075.5	Esters
620.4	Alkynes

Scanning Electron Microscope (SEM):



Electron Microscopes are scientific instruments that use a beam of highly energetic electrons to examine objects on a very fine scale. This examination can yield information about the topography (surface features of an object) morphology (shape and size of the particles making up the objects) composition (the elements and compounds that the object is composed of the relative amounts of them) and crystallographic information (how the atoms are arranged in the object).

TOXICOLOGICAL EVALUATION OF AIVAELI SAMOOLA CHOORANAM

Acute toxicity study

Swiss albino mice were treated with foxed doses of Aivaeli Samoola Chooranam 2000 and 5000mg/kg in 2% CMC as suspension (p.o) respectively. The mortality rate with a 24 h period was determined according to the OECD 425 method. Acute toxicity for *Aivaeli samoola chooranam* had been studied in mice and their behavioral changes are normal. Hence *Aivaeli samoola chooranam* is a safe herbal drug.

According to the results of acute toxicity test, the doses of 250 and 500 mg/kg were chosen for further experiments.

Table 7: Dose finding experiment and behavioral Signs of Toxicity of ASC

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	500	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	1000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	2000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	5000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

1. Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhoea 18. Writhing 19. Respiration 20. Mortality.

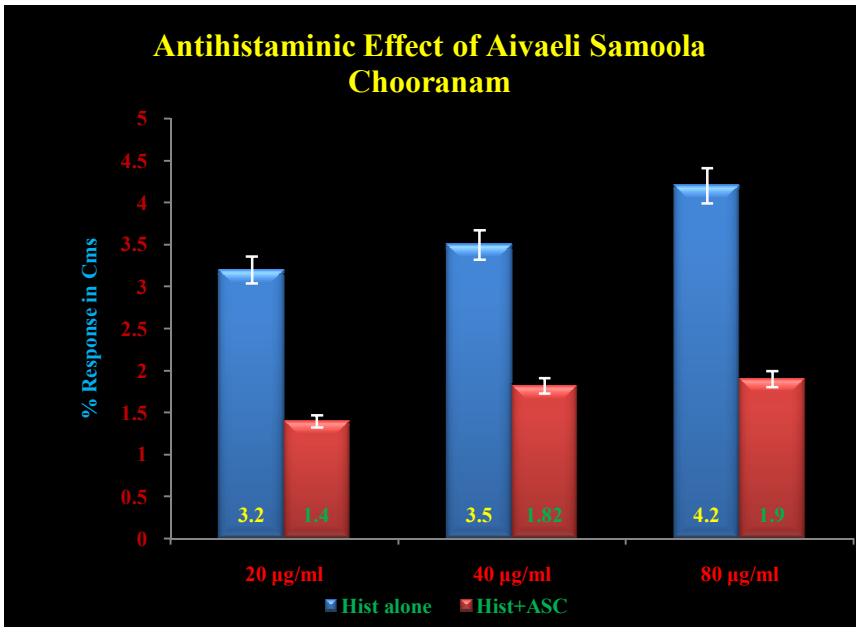
ANTI HISTAMINIC ACTIVITY OF AIVAELI AMOOLA CHOORANAM

In the present investigation, histamine produced dose dependent contraction as indicated in the kymograph. *Aivaeli Samoola chooranam* produced antagonistic effect on histamine induced contraction. Significance was observed at dose of 20, 40, 80µg/ml for histamine. The modified physiological salt solution containing *Aivaeli Samoola chooranam* (1000µg/ml) significantly inhibited ($p<0.01$) the contractile effect of histamine. Histamine is one of the important mediators of allergy, inflammation and bronchoconstriction. Targeting histamine, either prevention of its release from mast cells or use of histaminergic receptor antagonists becomes part of antihistaminic therapy in eczema. Histamine is an autocoid having profound physiological effect in the body.

Table-7: Effect of Aivaeli Samoola Chooranam on isolated Guinea pig ileum preparation

S. No	Dose of Histamine (µg/ml)	Maximum response in cms	
		Histamine alone	Histamine+Aivaeli Samoola Chooranam (1mg/ml)
1.	20 µg/ml	3.2±0.14	1.40±0.15**
2.	40 µg/ml	3.5±0.12	1.82±0.12**
3.	80 µg/ml	4.2±0.10	1.90±0.14**

Values are expressed in mean ± SEM, *p< 0.05 compared with histamine induced contraction (42mm as 100%); n=3.



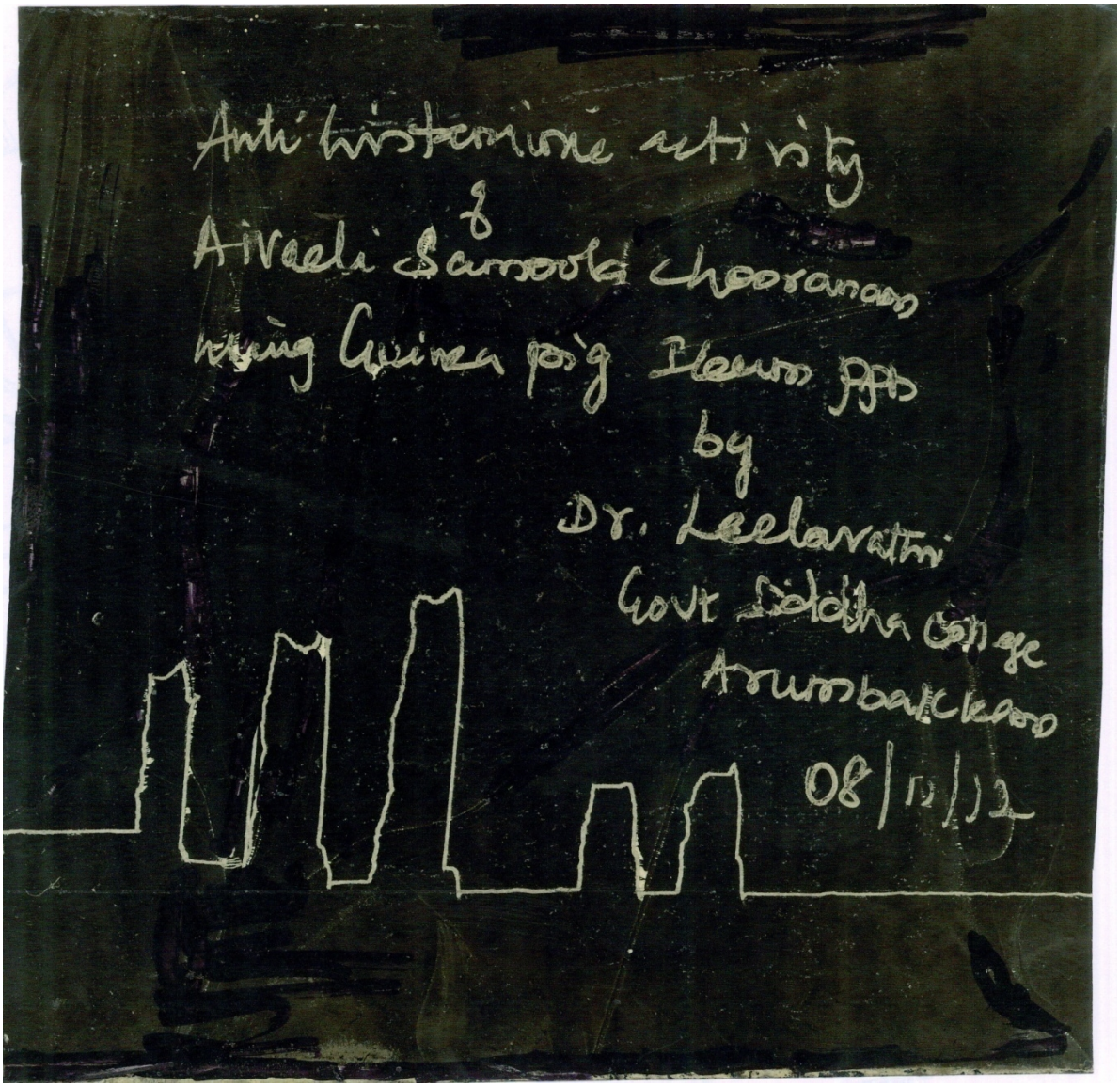


Fig No-5.A-Anti -histamine activity of ASC

ACUTE ANTIINFLAMMATORY ACTIVITY OF AIVAELI SAMOOLA CHOORANAM USING FORMALIN INDUCED METHOD IN RATS

Pain and inflammation are associated with the pathophysiology of various clinical conditions such as inflammation, arthritis, cancer and vascular diseases. Inflammatory reactions are not only the response of living tissues to injury and infection, but also are relevant to disease developments, such as asthma, multiple sclerosis, colitis, inflammatory bowel disease and atherosclerosis. Many natural products are used in traditional medical systems to relieve the symptoms from pain and inflammation. Formalin has been widely used as a noxious agent able to induce experimental inflammation for the screening of compounds possessing anti-inflammatory activity. This phlogistic agent, when injected locally into the rat paw, produced a serve inflammatory reaction, which was discernible within 30 min. The development of edema induced by formalin corresponds to the events in the acute phase of inflammation, mediated by histamine, bradykinin and prostaglandins produced under an effect of cyclooxygensase.

Oral administration of Aivaeli Samoola Chooranam significantly inhibited ($p<0.01$) the Formalin induced paw oedema in rats at both doses (250 and 500 mg/kg). At 250 mg/kg dose, 50% inhibition and at 500 mg/kg dose, 63.15% inhibition was observed. The group treated with Aspirin showed maximum inhibition of oedema, which was 69.23%. Inflammation is a complex process and various mediators e.g. prostaglandins, leukotrienes and kinins, platelet activating factor, etc. have been reported to be involved in the development if inflammatory diseases. Formalin assay is well studied for comparative bioassay of anti-inflammatroy agents, since the relative potency estimates obtained from most drugs tend to reflect clinical experience. Prostaglandins play a major role in the development of the second phase of inflammatory reaction which is measured around 3h of time.

The presence of prostaglandin in the inflammatory exudates form the injected foot has been well demonstrated. It is well known the that inhibition of formalin– induced paw oedema in rats is one of the most suitable test procedure to screen anti-arthritic and anti-inflammatory agent as it closely resembles human arthritis. Injection of formalin subcutaneously into hind paw of rats produces localised inflammation. The nociceptive effect of formalin is biphasic, an early neurogenic component followed by a later tissue

mediated response. The formalin induced paw oedema model in rats is known to be sensitive to cyclooxygenase inhibitors and has been used to evaluate the effect of non-steroidal anti-inflammatory agents which primarily inhibit cyclooxygenase involved in prostaglandin synthesis.

Based on these reports, it is inferred that the inhibitory effect of Aivaeli Samoola Chooranamon formalin- induced inflammation in rats in the present study may be due to inhibition of the enzyme cyclooxygenase, leading to inhibition of prostaglandin synthesis. The Aivaeli Samoola Chooranam exhibited significant dose dependent anti-inflammatory activity in the acute model of inflammation involving the induction of oedema in rat hind paw, comparable to the reference drug aspirin.

Table No-8 Anti-inflammatory effect of Aivaeli Samoola Chooranam in Formalin–induced paw edema

Group	Dose (mg/kg)	Increase of Paw volume in ml and % Inhibition		
		30min	60min	120min
Control	----	0.38±0.08	0.65±0.07	0.80±0.09
Aspirin	100	0.13±0.04** (65.78%)	0.20±0.04** (69.23%)	0.26±0.05** (67.50%)
ASC	250	0.19±0.04** (50%)	0.47±0.06* (27.69%)	0.42±0.04** (47.50%)
ASC	500	0.14±0.03** (63.15%)	0.28±0.04** (56.92%)	0.35±0.04** (56.25%)

n = 6 animals in each group *p<0.05 **p<0.01

From this study, it can be concluded that the *Aivaeli Samoola Chooranam* possess anti-inflammatory activity. The findings justify its use in traditional medicine to treat inflammatory and painful conditions.

ANTI MICROBIAL ACTIVITY OF *AIVAELI SAMOOLA CHOORANAM*

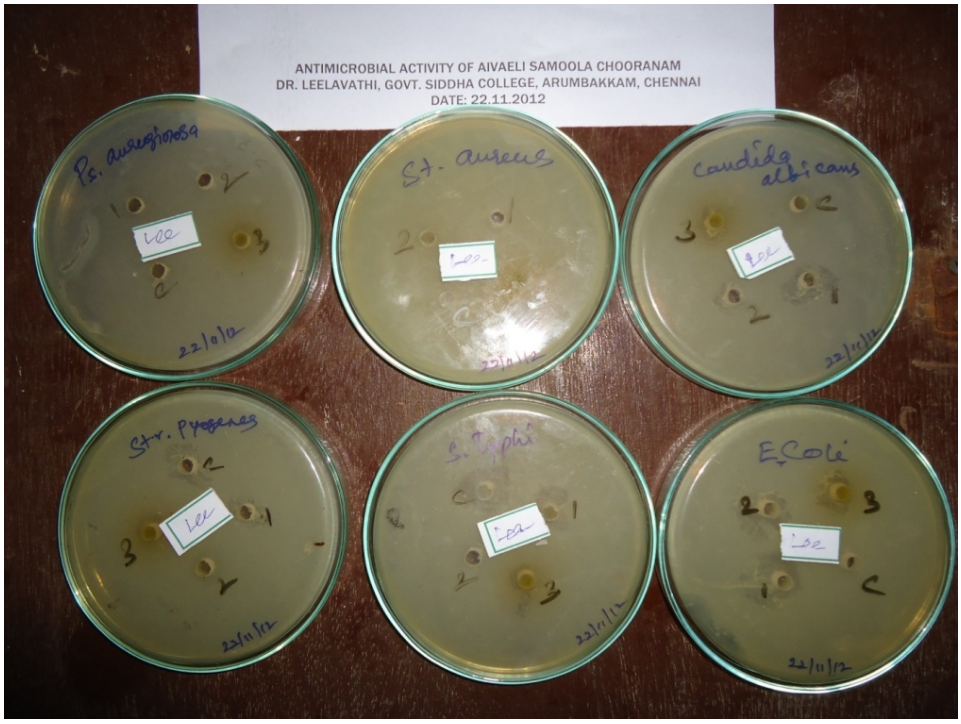


Fig.No.5.B Anti-microbial activity of ASC

The antibacterial and antifungal activity of *Aivaeli Samoola Chooranam* was tested. The maximum inhibition zone was observed for the *E.coli*, *S. typhi* and *Candida albicans* 7-9mm at the concentration range of 25-100µg/ml.

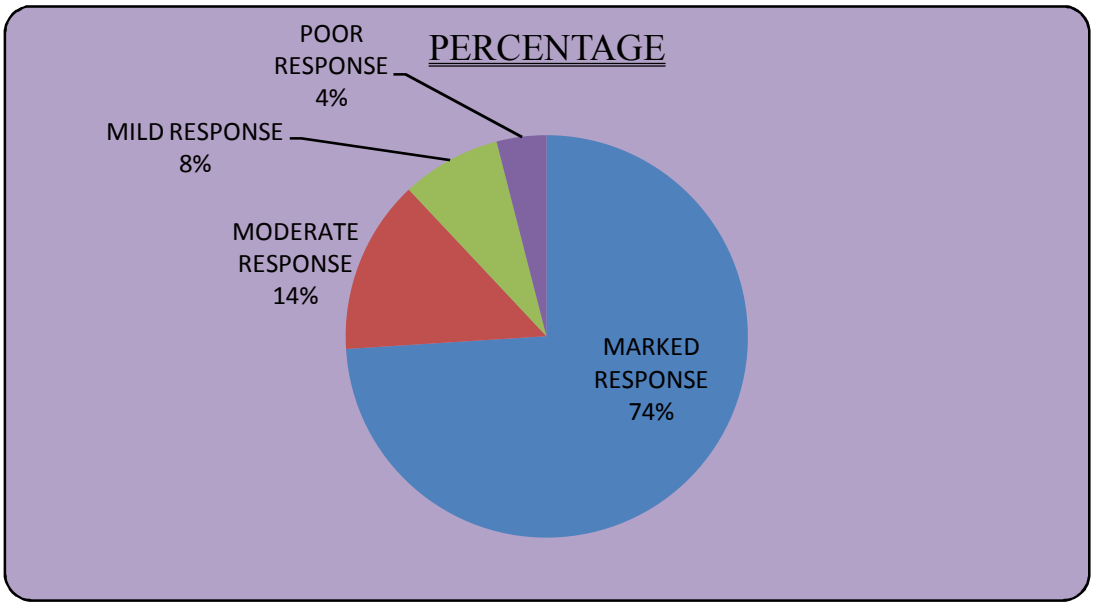
CLINICAL ASSESMENT

CLINICAL ASSESMENT OF *AIVAELI SAMOOLA CHOORANAM:*

50 patients from both sexes of various age groups were selected for clinical trial. Among 50 patients 40 patients were treated as out-patients, 10 patients were treated as in-patients. The selection was based on the inclusion and exclusion criteria. They were clinically diagnosed on the basis of siddha principles with modern laboratory findings.

Table No-9 Gradation result

SL. NO	LEVEL OF IMPROVEMENT	NO.OF PATIENTS	PERCENTAGE (%)
1.	Marked Response	37	74
2.	Moderate Response	7	14
3.	Mild Response	4	8
4.	Poor Response	2	4
TOTAL		50	100



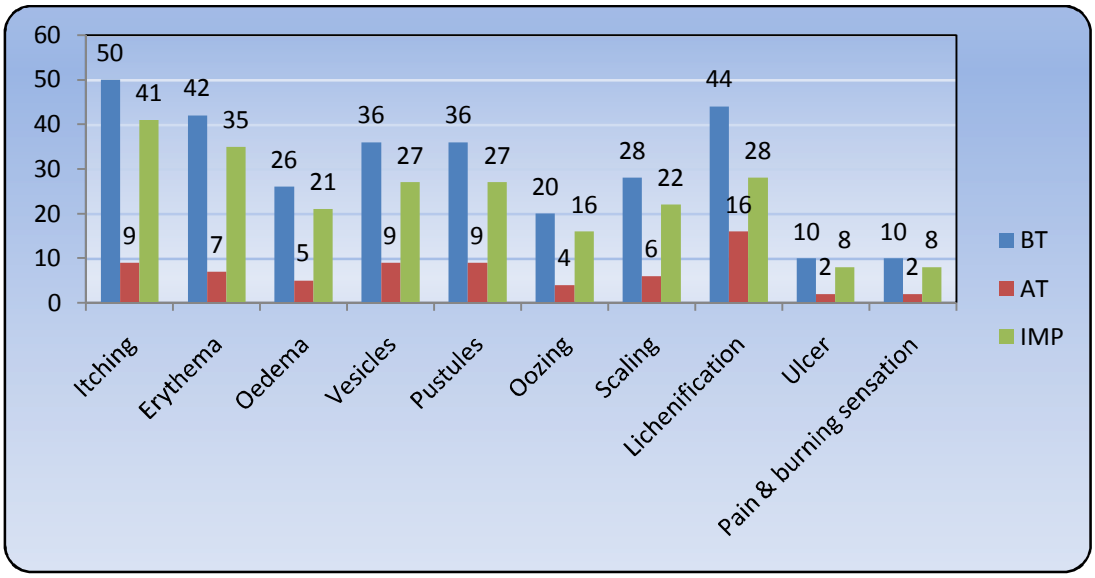
Inference:

Among 50patients,

- 37 patients had marked response.
- 7 patients had moderate response.
- 4 patients had mild response.
- 2 patients had poor response.

Table No. 10 (Improvement in signs and symptoms)

SL.NO	SIGNS AND SYMPTOMS	No of Patients			
		BT	AT	IMP	IMP %
1.	Itching	50	9	41	82
2.	Erythema	42	7	35	83
3.	Oedema	26	5	21	80
4.	Vesicles	36	9	27	75
5.	Pustules	36	9	27	75
6.	Oozing	20	4	16	80
7.	Scaling	28	6	22	78
8.	Lichenification	44	16	28	63
9.	Ulcer	10	2	8	80
10.	Pain & burning sensation	10	2	8	80



Inference

- 41 out of 50 patients were relieved from Itching
- 35 out of 42 patients were relieved from Erythema
- 21 out of 26 patients were relieved from Oedema
- 27 out of 36 patients were relieved from Vesicles
- 27 out of 36 patients were relieved from Pustules
- 16 out of 20 patients were relieved from Oozing

Fig.No.5.C- Comparison of before and after treatment with ASC in *Karappan* patient

STATISTICAL ANALYSIS

DESCRIPTIVE STATISTICAL FOR IMPROVEMENT IN SIGN & SYMPTOMS IN *KARAPPAN* (ECZEMA) PATIENTS

PAIRED "t" TEST RESULT:

EASI (ECZEMA AREA SEVERITY INDEX) SCORE

P value and statistical significance:

The two-tailed P value is less than 0.0001

By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence interval:

The mean of Before treatment minus After treatment equals 6.200

95% confidence interval of this difference: From 5.160 to 7.240

Intermediate values used in calculations:

t = 11.9769

df = 49

standard error of difference = 0.518

Group	Before treatment	After treatment
Mean	7.762	1.562
SD	4.326	0.985
SEM	0.612	0.139
N	50	50

6. CONCLUSION

The plant *Diplocyclos palmatus* (Aivaeli) is selected from the Siddha text *'Pathaartha guna vilakkam'* for the evaluation of its therapeutic efficacy on *Karappan*(Eczema). The plant of *Diplocyclos palmatus* (Aivaeli) authenticated by experts was subjected to step wise procedure of analysis like pharmacognostic study, physicochemical, phytochemical, chemical analysis to account the creditability of drug.

From the preliminary chemical analysis ,we came to know that the trial drug have Amino acid, Phosphate, Sulphate, Chloride, Iron, Calcium, Zinc, Alkaloids, Tannic acid. Zinc has potent wound healing activity. Zinc in *Aiveli samoola chooranam* might be the reason for its action in healing ulcers seen in Eczema.

Toxicological studies comprised of the evaluation of non-toxic dosage, acute toxicity on Swiss albino mice according to OECD guidelines.

Pharmacological study revealed the Anti-histamine, Anti-inflammatory, Anti-microbial activity of *Aivaeli Samoola Chooranam.*

The biologically active *Aivaeli Samoola chooranam* inhibiting the histhamine induced contraction on isolated guinea pig ileum preparation. Thus, the *Aivaeli Samoola chooranam* confirms the antihistaminic effect in presence of agonist like histamine which justify the H1 antagonistic traditional claim of *Aivaeli Samoola chooranam* in siddha system of medicine.

The antimicrobial activity of *Aivaeli Samoola Chooranam* was tested. The maximum inhibition zone was observed for the E.coli, S. typhi and Candida albicans 7-9mm at the concentration range of 25-100µg/ml.

The drug has shown significant improvement in Eczema patients. Overall result revealed that out of 50 patient 37 patient had marked response, 7 patient had moderate response, 4 patient had mild response and 2 patient had poor response. There were no new or unexpected safety events noticed during the course of the treatment.

From the above listed studies of *Aiveli samoola chooranam*, it can be concluded that the drug is safe and excellent medicine for management of *Karappan*.

7. SUMMARY

The plant *Diplocyclos palmatus* (*Aivaeli*) is selected from the Siddha text *'Pathaartha guna vilakkam'* for the evaluation of its therapeutic efficacy on *Karappan*(Eczema). The dissertation has started with an introduction in which Siddha fundamental theory behind selection of drugs for a disease, essentiality of Phytotherapy, the need for preclinical and clinical study on Aiveli for Karappan is signified.

The plant of *Diplocyclos palmatus* (*Aivaeli*) had been collected from Anthiyur Hills, Erode district, Tamilnadu and authenticated by experts.

Drug review disclosed the collection of Botanical aspect, Siddha aspect and Modern scientific aspects about the trial drug. Disease review explored the collection of siddha and modern literature about Eczema.

The drug was subjected to step wise procedure of analysis like pharmacognostic study, physicochemical, phytochemical, chemical analysis to account the creditability of drug.

Toxicological studies comprised of the evaluation of non-toxic dosage, acute toxicity on Swiss albino mice according to OECD guidelines.

Pharmacological study revealed the Anti-histamine, Anti-inflammatory, Anti-microbial activity of *Aivaeli Samoola Chooranam.*

Open clinical trial was conducted in 50 patients at Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Chennai. The drug has shown significant improvement in Eczema patients. Overall result revealed that out of 50 patient 37 patient had marked response, 7 patient had moderate response, 4 patient had mild response and 2 patient had poor response. There were no new or unexpected safety events noticed during the course of the treatment.

The final Discussion and conclusion chapters analyzed the dissertation. The conclusion chapter also provides a nutshell impact created by the study on Aiveli and made *Aivaeli samoola chooranam* as a scientifically proven drug of choice for *Karappan*(Eczema) to the medical society.

1. INTRODUCTION

Siddha system is the treasure dedicated to world by *Siddhars* for keeping the people at the state of physical, mental and social well being. Siddha strongly advocacies every physician to look into "what kind of person is affected by an ailment is most important than what kind of illness he has". This perspective devises the protocol of every treatment in Siddha. This unique fundamental is the subtle strength and rationale behind the existence of this system since antiquity. The proper combination and harmony of the three humours- *Vali, Azhal, Iyam* in their qualities and right proportion are responsible for maintaining good health. When these three humours are disturbed by food, life style modification or any other disorders, they are provoked and disease manifest.

Regularizing the deranged these three humours (*Mukkutram*), Strengthening them, balancing the distribution of them by food, life style and medicine is the treatment methodology followed in Siddha to handle a diseased patient. As per T.V.Sambasivampillai Dictionary, *Marunthu* (medicine) is a substance that helps to alleviate or eradicate the disease, gives strength to the body and normalises the function of the body. Making use of natural sources like plants, metal and minerals, animal products, medicines are prepared. Depending upon mode of application, these medicines are grouped under two categories:

1. *Agamarunthugal* (Internal medicines) - 32

2. *Puramarunthugal* (External medicines) - 32

In addition, *Muppu, Rasavatham, Thiravagam, Seyaneer, Maranam*, etc., are some special wings under Siddha pharmacology to prepare a medicine at its peak therapeutic efficient form. Siddha answers for many of challenging diseases of present world using these kinds of wide ranged medicine preparations. One such medicine is ***NAVACHARA CHUNNAM*** which is suggested for *Soothagakattu,* ***Soothagakatti,*** *Magotharam, Neerambal And Pandu* mentioned in *Anuboga Vaithiya Navaneetham.*

Chunnam is a form of internal medicine, placed superior than *Parpam* and *Chenduram*, has 500 years shelf life. *Chunnam* are medicaments prepared by heat and calcinations following the procedure stipulated in the recipes. They possess alkaline properties similar to that of lime stone. *Navacharam*, one of *Karasaram* (Mineral) with more therapeutic effects, when made into *Chunnam,* can stand as potent medication for

Soothagakatti. It is a disorder mentioned in Siddha, which is closely related to polycystic ovarian syndrome (PCOS), one of the most common female endocrine disorder and an important cause of female infertility.

The W.H.O defines reproductive health as "it is a condition in which the reproductive process is accomplished in a state of complete physical, mental and social well-being and is not merely the absence (or) disorders of the reproductive process". Polycystic ovarian syndrome (PCOS), which affects female reproductive health, is a multisystem endocrinopathy with ovarian expression of metabolic disturbance and a wide spectrum of clinical features, such as hyperandrogenism and obesity along with metabolic disorders (*Shaw et al,* 2007). It occurs mostly in the age group between 20 and 30 (*Potemkin)* The prevalence of PCOS is estimated at 5–10% of women in childbearing age. (*Franks S,* 1995*).*

The syndrome was described by Stein and Leventhal in 1935, although Polycystic degeneration of the ovaries had been reported by Slavyansky in 1893, Lesnoi in 1928 and Gigoisky in 1930 (*V.Potemkin,*) The need to establish universally accepted diagnostic criteria led to the Rotterdam criteria for PCOS in 2003 (*The Rotterdam ESHRE/ASRM-Human Reproduction, 2004)* but no optimal treatment was defined for infertile women with PCOS even then.

Several studies have recommended that insulin resistance plays a significant role in the pathogenesis of the syndrome. Insulin resistance is now recognized as a major risk factor for the development of type II diabetes mellitus (*Reaven GM. 1988*). As an effect of insulin-resistance, women affected by PCOS often present abnormalities of glucose metabolism and lipid profile, and have an increased risk of type II diabetes and cardiovascular disease over-time. Women with PCOS are at increased risk of endometrial cancer. (*K Bhasker rao et al, 1996*)

The drug of choice available for management of this female endocrine disorder, in present medical world, is very less. Clomiphene citrate is the commonly prescribed drug to PCOS women for its ovulation inducing activity. The common adverse reaction of Clomiphene citrate is hot flushes. The important drawback is that it causes (i) Ovarian enlargement and cyst formation due to overstimulation, which may lead to rupture and internal hemorrhage. (ii) Multiple ovulation, resulting in multiple pregnancies and fetal wastage. Rarely it may cause restlessness, blurring of vision and alopecia. (*R.S.Satoskar*)

In this present scenario, the need of hour is to explore a drug with high therapeutic efficacy for treatment of PCOS with no or less side effects. Siddha answers this challenge with "*Navachara Chunnam"*. The author hopes that studying the effect of *Navachara Chunnam* on PCOS will discover a new drug of choice to add strength for the fight of medical world against PCOS, in turn female infertility.

2.AIM AND OBJECTIVES

AIM

To justify the ancient Siddha drug for remedial of Polycystic Ovarian Syndrome with its supreme formulation and provide good progress. The purpose of the present study was aimed at evaluating the activity of *Navachara Chunnam* for its naturally curing PCOS through pre clinical and clinical aspects. In present medical world there is a need for proper treatment for PCOS. The aim of this study is a new drug evaluation for treatment of PCOS.

OBJECTIVES

The key objectives of the study are:

- To have a collective review of the literature.
- To prepare the drug according to Siddha classical text.
- To subject the drug to physico-chemical standardization.
- To analyze the drug chemically for detection of acid and basic radicals.
- To focus the drug for analytical assessment.
- To study the toxicity profile of *Navachara Chunnam* according to OECD guidelines.
- To determine the pharmacological activity (Ovulogenic effect) of *Navachara Chunnam.*
- To assess the therapeutic potential of the drug through clinical trial for the management of PCOS
- To analyze all the above study results to evaluate the advantage of *Navachara Chunnam.*

3. REVIEW OF LITERATURE

3.1. LITERATURE REVIEW OF DRUG

❖ நவச்சாரம்

- நவச்சாரம் காரசார வர்க்கத்தினைச் சார்ந்தது.

உங்கந்தா னுப்புவகை இருபத்தைந்து

என்று போகர் கூறுவதிலிருந்து காரசாரம் இருபத்தைந்து என்று அறியலாம்.

"பொருத்துகின்ற நவச்சாரம் சக்திச் சாரம்

.....

.....தீயின் கம்பி

கருத்தொகையி லிவையிருபத் தைந்தும் வாத

காரசா ரத்துறையாய்க் கண்ட வாறே"

(போகர் காரசாரத்துறை)

- நவச்சாரம் அப்புவின் கூறாகும்.

" .....ஆணிப்பார் நவச்சாரம் சக்திச் சாரம்

அப்புவென்று சொல்வார்க ளறிந்து கொள்ளே"

(போகர் காரத்துறை) .

- செயநீருக்கு ஆதிப்பொருள் நவச்சாரம் ஆகும்.

❖ நவச்சாரப் பெயர்கள்

ஆகுமே நவச்சாரப் பேரைக்கேளு

அடுக்காகும் நவசித்தி சாரமானோன்

வாகுமே சலக்கூர்மை வாருத்திக்குள் கப்பல்

வழங்கினோன் ஒன்பதிட வமுரியானோன்

வேகு மாய் சுந்தரன் மேகநாதன்

மெய்யான வாதத்துக் கொப்பாய் நினறோன்

போகுமே வாதமென்ற வாருதிக்குள் நாதன்

பேரான செயநீர்க்கு நாதனாமே

ஆமென்ற வாதத்திற்கு சிரோமணியாய் நின்றோன்

அசுரனாஞ் சகல குருஅக் கினிதீயோன்

வேமென்ற துருசுக்கு மேற் குருவானோன்

விடுபட்ட நவசாரி கடுஞ்சாரி யானோன்

போமென்ற வாதத்தை சமைக்குகின்றோன்

பேரான கெங்கையுகட குணமுள்ளோனாம்

நாமென்ற சக்தியிட கூறாய் நின்றோன்

நவச்சாரப் பேரெல்லாம் நாட்டினேனே.

(போகர் நிகண்டு-1200)

வேறு பெயர்கள்

- இஷ்டிகை
- சல்லிகை
- சூளிகை
- படு

– (டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004)

❖ நவச்சாரத்தின் நிறம்,சுவை மற்றும் மணம்

- நிறம்–அழுக்குப் படிந்த நிறமாகவும் அல்லது கபில நிறமாகவும் இருக்கும்
- சுவை–புளிப்புச் சுவையுடன் கசப்பாக இருக்கும்
- மணம்–மூத்திர வெகுட்டலுடையதாகவும் இருக்கும்
- நவச்சாரம்-ஆண் சரக்கு. இதற்கு பெண்சரக்கு வெங்காரம்.

-(சி.கண்ணுசாமிப் பிள்ளை,2011)

❖ நவச்சாரம்-சுத்தி முறைகள்

❖ நவச்சாரத்தை வெந்நீரில் கரைத்து, சூடாயிருக்கும்போது வடிகட்டி, குளிர ஆறியபின் வாய் அகன்ற பாத்திரத்தில் விட்டு வெய்யிலில் வைக்க உப்பு உறையும்.குன்றிமணி வேரை இத்துடன் இட்டு புட்டியில் வைக்க வெகுட்டல் போகும்.

❖ கோமூத்திரத்தில் கரைத்து, வடிகட்டிச் சுண்ட எரித்து வெய்யிலில் உலர்த்தி எடுக்கச் சுத்தி ஆகும். -(டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004).

செய்கை

- உடல் தேற்றி (குறைந்த அளவில் நாள்படக் கொடுத்தால்)
- வெப்பமுண்டாக்கி (அதிகளவில் கொடுக்க)
- கோழையகற்றி
- வியர்வைபெருக்கி
- விரணமுண்டாக்கி
- பித்தமகற்றி
- முக்கியமாக நிண நரம்புகள், மாமிசக் கிரந்திகள் மீது தன் வேகத்தைச் செலுத்தும்.

சாரத்திற்குச் சத்துரு

கல்லுப்பு, இந்துப்பு, படிகாரம், வளையலுப்பு, இரும்பு, காந்தம், வங்கம்,அண்டத்தோல், சுக்காங்கல், சிலை, அப்பிரகம், சவுட்டுப்பு, கிளிஞ்சல்.

சாரத்திற்கு மித்துரு

பூரம், மனோசீலை, கபரி, நிமிளை, பண்ணை,கௌரி, இலிங்கம். (சி.கண்ணுசாமிப் பிள்ளை, 2011)

பொதுகுணம்

"குன்மம் குடற்சூலை கொல்லும் மகோதரத்தை
வன்மையுறுங் கல்லடைப்பை மாற்றுங்காண்-சன்மக்
கவிச்சமுத் தோடங்க கனவாத நீக்கும்
நவச்சார மாதே நவில்.

பொருள்:

வயிற்றுவலி,குடலில் குத்தல்,பெருவயிறு,கல்லடைப்பு, சருமத்தில் புலால் நாற்றம்,திரிதோடம்,கனவாயு போக்கும்.மேலும்,உப்பிசம், கல்லீரல் வீக்கம்,பீலீக நோய்,முகச்சந்தி,இரத்த காசம்,சூரியாவர்த்த வாதம்,சூதகக்கட்டு, கக்கிருமல்,விடாக் காய்ச்சல்,இவைகட்கும் உபயோகிக்கலாம்.(டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004).

அளவு

21/2 குன்றி(325மி.கிராம்) முதல் 71/2 குன்றி (975 மி.கிராம்) வரையாகும்.அதிக அளவில் கொடுக்க பேதியாகும்.(டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004).

உபயோகம்

கருப்பவாயு,கருப்பையின்வலி,கருப்பையின்வீக்கம்,சூதகக்கட்டு,பித்தவாந்தி, வாந்திக்குப்பின் காணும் தலைநோய், தலைக்குத்தல் இவைகளுக்கு நவச்சாரத்தைக் கருப்பூரங்கலந்த நீரில் தினம் இரண்டு மூன்று முறை கொடுக்க நல்ல குணமுண்டாகும்.(டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004).

VERNACULAR NAMES OF NAVACHARAM

Tamil	–	Nava-charam;Nava-charum
Sanskrit	–	Navasara, Navasagara, Chulika lavana.
English	–	Sal Ammoniac.
Arabic	–	Armina, Milhunnar.
Punjabi	–	Noshadar.
Kashmiri	–	Nausadan.
Hindi	–	Navasadara, Nousadar.
Bengali	–	Navasagara, Nishadal, Duk.
Gujarati, Mah. & Kon.	–	Navsagar.
Malayalam. & Telugu	–	Navasaram
Burm.	–	Lovas; Zarasa

As obtained in the bazaars is generally very impure in dirty white or brownish translucent cakes, “as it is manufactured from a kind of clay found at Karnal in the Punjab” – (Chopra). It is obtained by the combustion of excretions of various animals or of animal matters or by burning coals or common salt. It is a secondary product in the manufacture of coal gas. It is generally obtained in India from unburnt extremities of brick-kilns in which manure of animals, especially camel’s dung is used as fuel. To this, coal and common salt are added and sublimed. It is thus obtained in white granular crystals or transparent masses.

It is readily soluble in water and is highly deliquescent. It has a saline, disagreeable, nauseous and pungent taste. It can be purified and made into a powder by dissolving in hot water and evaporating to dryness and then bottling.

ACTION

Alterative, expectorant and cholagogue in small doses.

In large doses purgative. It has a marked stimulating action on the mucous membranes, increasing their secretion also on the absorbent system and on gland structures.

MEDICINAL USES

It relieves hepatic congestion and modifies hepatic secretions; useful is cases of hepatic abscess, chronic hepatic congestion and in dropsy connected with the liver and **ovarian diseases**; in cirrhosis and in jaundice from catarrh of the bile ducts.

For hepatitis, sal-ammoniac 8 to 15 grains, mixed with 105 grains of Absinthium (worm wood) rubbed well in a mortar with a little water and given in a single dose will give relief (Hakim & Vaidyan).

In gastric catarrh in biliousness with coated tongue, foetid breath, flatulence etc., in bronchial and vesical catarrh, in chronic pharyngitis with glairy mucous secretions and whooping cough it is valuable, combined with liquid extract of glycyrrhiza syrup of Country liquorice and with a few grains of powdered cinnamon, in cases of whooping cough.

In amenorrhoea, dysmenorrhoea, gleet, leucorrhoea, chronic dysentery and other similar chronic discharges from lungs, stomach and other internal organs it is given dissolved in *conjee* water (2 drachms to a pint) in wineglassful doses every second or third hour. “In hysteria, nervousness, jaundice and other live complaints and gastric catarrh, doses of 10-20 grains three times daily are beneficial. It is often prescribed as a stimulating expectorant in chronic bronchitis and in pneumonia in the stage of resolution- (Chopra).

In various forms of neuralgia, in chronic liver diseases, organic or functional, in rheumatic affections of the face etc., it is given in infusion of Indian Sarsaparilla; in intermittent fever, in sick or nervous headaches, acute alcoholism and in delirium tremens its action is very marked, given dissolved in camphor julep. In dropsy due to

liver disease and in that following fevers, it is administered with infusion of Moringa or decoction of Astercantha.

As an alterative it acts slowly modifying the nutrition of the tissues; it is a useful agent in chronic inflammatory diseases of the glands such as thyroid body, liver and spleen and in induration of the uterus, ovaries and the prostate and externally for fomentation in the form of a lotion (1 in 80). In urinary diseases chiefly where the urine is full of lithates it is very useful.

Externally its solution combined with nitre is a nice cooling and stimulant application to the head in headache, “sprains, rheumatism, lumbago, sciatica” (Chopra), mania and apoplexy, and for inflamed erysipelas and hernia tumours; in inflamed hydrocele, indolent tumours, in enlarged glands, in (mammary) milk abscesses occurring after confinement and abscesses in other parts of the body before formation of matter, in chronic skin diseases and as a dressing for bruises and blows on the eye (black eye). For milk abscesses etc., it is used as lotion.

With Arrack and rose-water (1 in 8 and 160 parts respectively). Mixed with sulphide of arsenic, it is used as an application to scorpion bites. As an inhalation in affections of the air passages its vapours produced by heating a drachm of it on a dish, are useful. Ammonium Chloride is recommended for local application in case of cataract.(Dr.K.M. Nadkarni)

சேரும் மருந்துகள்

❖ போஜன சஞ்சீவி லேகியம்

திப்பிலிகா சாமிளகு சீர்வெடி யுப்போமம்
செப்பத் தொடியிந்து சேருங்கல்-லுப்போடு
சோற்றுப்பு வெங்காரம் சொல்நவாச் சாரமுடன்
ஏற்ற சவுக்கார மெண்.

எண்ணும் பெருங்காயம் ஏற்கக்கி ராம்போடு
உண்ணுங்கோஷ்டம் சுக்குயர்மோடி-நண்ணிப
நையப் பொடித்து நறும்பூண்டில் தோலுரித்து
உய்யபல மோரைந்தா வோது

ஓதப் பனங்கட்டி ஓக்க நறுந்தேனும்
வீதம் பலமைந்து விட்டரைத்துச்-சேதமிலாச்
சுண்டைக்காய் போலளவு சொல்ல விருநேரம்
கொண்ட பயன்றானே கூறு.

கூறும் மடவாரின் கோரில்வந் தூரத்தில்
சீறும் வாலியோடு சேர்வாய்வு – வீறும்
வலிகுன்மம் பித்த மதிகரித்த வாய்வாம்
நலியோடு மென்றதனை நாடு.

விளக்கம்

சேரும் சரக்குகள்

திப்பிலி,கஞ்சா,மிளகு,வெடியுப்பு,ஓமம்,வளையலுப்பு,இந்துப்பு,கல்லுப்பு,சோற்றுப்பு,வெங்காரம்,நவச்சாரம், உழமண், பெருங்காயம்,கிராம்பு, கோஷ்டம்,சுக்கு, மோடி வகைக்கு 1 பலம், உரித்த பூண்டு பலம்-5, தேன் பலம்-5

இவைகளைக் கல்வத்திலிட்டு லேகிய பதமாக அரைத்து வைத்துக் கொண்டு வேளைக்கு சிறு சுண்டைக்காய்ப்பிரமாணம் தினம் இருவேளை உட்கொள்ள ஸ்திரீகளுக்கு மாத விலக்கத்தில் வரும் சூதகவாய்வின் வலி, குன்மவயிற்றுவலி, பித்தவாய்வு, மந்தம், அஜீரணம் தீரும்.

(சி.கண்ணுசாமிப் பிள்ளை;2009)

❖ பஞ்சலவணத் திராவகம்

பாராரும் வெடியுப்புங் கெடுப்பா யொன்று

பார்க்கவே சீலமரைக் காரம் காலாம்

நேராருஞ் சாரமதிங் கரைக்கா லோடு

நிகழ்த்துகறி யுப்பதுவே வீசமாகும்

சீராருந் திராவகமே யினிது வாங்கிச்

சேர்க்கவே சலத்திலெழு துளியாங் காறும்

சூராருஞ் சூதகனோய் வாய்வு குன்மம்

தொந்தித்த மார்புநோய் தொலையுந் தானே.

பொருள்

வெடியுப்பு-1 சேர்

படிகாரம்-1/2 சேர்

வெங்காரம்-1/4 சேர்

நவச்சாரம்-1/8 சேர்

கறியுப்பு வீசம் சேர் அளவாகக் கல்லுரலில் போட்டுக்கடப்பாறையால் தூளாக இடித்து, மட்கடத்தில் இட்டு மண் வாலையைச் செருகி சீலை செய்து,காய்ந்தபின் திராவகம் வாங்கவும்.

அளவு; 7 துளி குளிர்ந்தசலத்தில் கலந்து இருவேளை

தீரும் நோய்கள் - ஸ்திரீகளுக்குண்டாகும் சூதகவலி, வாய்வு, குன்மம், மார்புநோய் நீங்கும்.(சி.கண்ணுசாமிப் பிள்ளை;2009)

❖ சார மெழுகு

சேரும் சரக்குகள்

சாரம்	பலம் 3
கொம்புக்கள்ளிமரப்பால்	பலம் 1
சுத்தி செய்த வாளம்	பலம் 1
சிற்றாமணக்குப்பால்	பலம் 3

செய்பாகம்;

முதலில் சாரத்தைக் கல்வத்தில் இட்டு கொம்புக்கள்ளிமரப்பால் விட்டு அரைத்து அதன்பின் வாளமும் சிற்றாமணக்குப் பருப்பு கூட்டி நன்கு அரைத்து மெழுகுபதத்தில் வழித்து வாயகன்ற புட்டியில் பத்திரப்படுத்தவும்.

பிரயோகம்;

தேக திடத்திற்கு ஏற்றவா 1-2 மிளகுப் பிரமாணம் பனைவெல்லத்தில் வைத்துக் காலை நேரத்தில் கொடுக்க 7-8 தடவை பேதியாகும்.இந்த மெழுகால் பேதி அதிகமாயின் மறுநாள் அளவைக் குறைத்து கொள்க.பேதி சரிவர ஆகாவிடின் சிறிது அளவை அதிகபடுத்திக் கொள்க.

தீரும் வியாதி; வாத நீரை வெளிப்படுத்தி கால் வீக்கம், அண்ட வாதம், வயிற்றிலுள்ள கட்டி, பாண்டு, மகோதரம், சூதக வாயு நீங்கும்.

(சி.கண்ணுசாமிப் பிள்ளை;2012)

கலிங்காதி யெண்ணெய்

குன்மவகை தீருதற்குக் கலிங்காதி குடிநெய்
குணமாகச் சொல்லுகிறேன் புலத்தியனே கேளாய்
கன்ம மென்ற தும்மட்டிக் காய்ச்சா றப்பா
கருவாகப் படியிரண் டாவி னீர்தான்
தன்மமென்ற படியிரண்டு வெள்ளாட்டு நீர்தான்
தப்பாமல் படியொன்று கூட்டிச் சேர்த்துப்
பன்மனென்ற வாமணக்கி னெய்யு மப்பால்
பகராதே படியிரண்டு கூட வாரே.

வார்த்தப்பால் கடுக்காயுங் கடுகு ரோணி
வளமான வாய்விளங்கந் திரிகடுகு மேலம்
ஏத்தப்பா விந்துப்பு வளைய லுப்பு
இதமான கல்லுப்புச் சவுட்டினுப்பு
காத்தப்பா நவாச்சார மெவாச்சாரங்க காரங்
கலங்காதே யப்பளா காரங் கூட்டிப்
பார்த்தப்பா வால்மிளகு யானைத் திப்பிலியும்
பாங்கான வெள்ளுள்ளிப் பருப்பு மாமே.

ஆமப்பா நிலவாகை கண்டங் கத்திரி
அப்பனே வெள்ளைச்சா ரணையின் மூலம்

நாமப்பா சத்திச்சா ரணையின் மூலம்
நலமாக வரைப்பலமா யரைத்துக் கொண்டு
தாமப்பா நொச்சிச்சாறு பசுமஞ்சள் சாறுந்
தளமான விஞ்சிச்சாறு குமரிச் சாறு
வேமப்பா படியரையாய்க் கூட விட்டு
விருதான கடைச்சரக்குக் கழஞ்சு மூன்றே.

மூன்றப்பா லரைத்தந்தநெய் தனிற் கரைத்து
முதிராம லடுப்பப்பேற்றி மெழுகுபத மானால்
ஏன்றப்பா கலசமதில் வடித்து வைத்தே
என்னசொல்வே னரைக்கால்சேர் வீத மாகக்
கான்றப்பா கொண்டுவரப் பத்து நாள்தான்
கவிசையொடு பீலிகையுங் கரைந்து போகும்
ஆன்றப்பா பெருவயிறு வாயுக் கட்டி
அணுகாது மகோதரங்க ளற்றுப் போகுமே

அற்றுபோம் வாயுவென்ற திரட்சி யெல்லாம்
அப்பனே குணமாகு மெட்டு வாயு
நற்றுப்போங் கர்ப்பவலி கர்ப்ப சூலை
நாடாதே யிசிவுபுழு நழுவி வீழும்
கற்றுப்போங் கைகாலில் கட்டுச் சூலை
கடல்புக்குங் குந்துவலி காண தோடும்
பற்றுப்போம் வயிற்றிலுள்ள வியாதி யெல்லாம்
பறக்குமடா வின்னமொன்று பகரக் கேளே.

விளக்கம்;

ஆற்றுத்தும்மட்டிக்காய் படி-2, ஆவின் நீர் படி -2, வெள்ளாட்டு நீர் படி-1, ஆமணக்கெண்ணெய் படி-2 இவைகளை ஒன்று கூட்டி ஒர் தைல பாண்டத்திலிட்டு,அதில் கடுக்காய், கடுகு ரோகிணி, வாய்விளங்கம் ,சுக்கு, மிளகு, திப்பிலி, ஏலம், இந்துப்பு, வளையலுப்பு, கல்லுப்பு, சவுட்டுப்பு, நவச்சாரம், எவாச்சாரம், அப்பளாகாரம், வால்மிளகு, ஆனைதிப்பிலி, வெள்ளைப்பூண்டு, நிலவாகை, கண்டங்கத்திரி, வெள்ளைச்சாரணை, சக்திச்சாரணைக்கிழங்கு, வகைக்கு பலன் ½ வீதம்

பால் விட்டரைத்துச் சேர்த்து, நொச்சிச்சாறு, பச்சைமஞ்சள் சாறு, இஞ்சிச்சாறு, சோற்று கற்றாழைச் சாறு, வகைக்குப் படி-1/2 சேர்த்துக் கலந்து, 3 கழஞ்சு பெருங்காயத்தையும் அரைத்துக் கலந்து அடுப்பிலேற்றி எரித்து வண்டல் மெழுகு பதமாகும் பதத்தில் வடித்துக்கொள்க.இதில் 1/2 முதல் 1 பலம் வீதம் 10-நாள் பத்தியத்துடன் அருந்த கவிசை, பீலீகை, பெருவயிறு, வாயுக்கட்டி, மகோதரம், வாதப்பிணி, கருப்பைவலி, கருப்பைசூலை, கருப்பக்கிருமி, குன்மக்கட்டி, வயிறு சம்பந்தமான பிணிகள் முதலியன நீங்கும். (அகத்திய முனிவர் அருளிச்செய்த வைத்தியரத்தினச் சுருக்கம்)

❖ லவணத் திராவகம்

ஓதப் பார்வெடி யுப்பறு சீனமும்
தீதி லாத்திரி சேர்த்திடு சாரமும்
பூதி லாக்கறி யுப்பியிவை பாதியே
வேதை யாக்குந் திராவகம் வேண்டுமே

வேண்டு திராவகந் தன்னை விரும்பிடப்
பாண்டு குன்மம் பறித்திடு பீலீகை
ஈண்டி ரோமென் றெழுன்பி யலைகடல்
தாண்டு மென்று தவமுனி சொற்றதே

பொருள்- வெடியுப்பு 6 எடை
படிகாரம் 3 எடை
சாரம் 11/2 எடை
கறியுப்பு 11/2 எடை

கல்லுரலில் போட்டு நன்றாய் இடித்து, மட்கடத்தில் இட்டு,வாய்க்குப் பொருத்தமான வாலையைச் செருகி மண்சீலைசெய்து, காய்ந்தபின் திராவகம் வாங்கவும். அளவு-3-5 துளி வரையில் ஒரு வாய் சலத்தில் விளாவித் தினம் இருவேளை உண்டுவரின் ஜீரக்கட்டி, சூதகக்கட்டி, குன்மம், பாண்டு, முதலிய ரோகங்கள் நிவர்த்தியாகும். இச்சாபத்தியம்.

ஊமத்தை

Botanical name - *Datura innoxia*

சுவை - கைப்பு

தன்மை - வெப்பம்

பிரிவு - கார்ப்பு

செய்கை

வாந்தியுண்டாக்கி (Emetic)

இசிவகற்றி (Antispasmodic)

துயரடக்கி (Anodyne)

மூர்ச்சையுண்டாக்கி (Narcotic) (குணபாடம் மூலிகை வகுப்பு)

பொதுகுணம்

நாய்க்கடியாய் வந்து நலிசெய் விரணமும்போம்
வாய்க்குழிப்புண் கட்டிகளு மாறுங் காண்-தீக்குணத்தைச்
சேமத்தில் வைத்திலிடந் தீருமுத்தோ டங்களறும்
ஊமத்தை யின்குணத்தை யுன்னு.

(அகத்தியர் குணவாகடம்)

குணம்

இதன் இலையை உலர்த்திப் பொடி செய்து 32 மி.கி அல்லது 100 மி.கி அளவு உள்ளுக்குக்கொடுக்க,இரைப்பு நீங்கும். சிதைத்த விதை 42 கிராமுக்கு, எண்ணெய் 325 மி.லி சேர்த்து ஏழு நாள் வரையில் அரைத்தரைத்து வெயிலில் வைத்து, 8- ம் நாள் வடித்து, அடிவயிற்றில் தடவ, சூதக வயிற்றுவலி, நீர்த்தாரை எரிவு நீங்கும்.

சேரும் மருந்துகள்

- தேரையர் முறைபடி இரசபற்பம் செய்ய கருவூமத்தை பயன்படுகிறது (டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004)
- சுராங்குசம் என்னும் மாத்திரை செய்ய பயன்படுகிறது.(சி.கண்ணுசாமிப் பிள்ளை,2011)
- கோமேதக பற்பம் கருவூமத்தன் சாறுவிட்டு அரைத்து செய்யப்படுகிறது. (சி.கண்ணுசாமிப் பிள்ளை,2011)

சோம்பு

Botanical name	-	*Pimpinella anisum*
சுவை	-	மணமுடன் கூடிய கார்ப்பும், இனிப்பும்
தன்மை	-	வெப்பம்
பிரிவு	-	கார்ப்பு

செய்கை

அகட்டுவாய்வகற்றி

பசித்தீத்துண்டி

குணம்- சூதகவாயுவை கண்டிக்கும்.(குணபாடம் மூலிகை வகுப்பு)

சுண்ணம்

சுண்ணமருந்து(calcined compound)

In Tamil medicine several kinds of lime are used. They go by the name of the substance used to prepare the lime. They are lime from calcined Bivalve shells, snail shells, conch shell, crab shell, egg shell, pearl oxyster shell etc(T.V. Sambasivam pillai)

சுண்ணத்தின் ஆயுட்காலம்

“.....

றெள்ளிடாச் சுண்ணம்ஐந் நூறுகற் பஞ்சத்து

.....

ஆயுட்காலம் ஐந்து நூறு ஆண்டுகள் ஆகும்.”

(டாக்டர் இரா.தியாகராஜன்,L.I.M ;2004)

சுண்ணத்திற்கு ஆதி

“ .....

வாத்திடவே வீரமொடு புனுகு சீனம்

மக்களே யிவைமூன்றும் சுண்ணத் தாதி”

(காரசாரத் துறை)

சுண்ணம் செய்யப்பயன்படும் கருவிகள்

- மண் மூசை
- வச்சிர மூசை

- ஆட்டுத்தோலில் செய்யப்பட்ட ஒற்றைத் துருத்தி
- பஞ்ச சுண்ணக் குகை. (போகர் நிகண்டு-1200)
- சுண்ணமாக்கும் மூலிகை
- வேலிபருத்தி (குணபாடம் மூலிகை வகுப்பு)

❖ சுண்ணம் செய்யுங்காலங்கள்

- பங்குனி
- சித்திரை (டாக்டர் க.சு.உத்தமராயன்)

❖ சுண்ணத்தின் தன்மைகள்

"பாருநீ சுன்னமெல்லாம்
பறந்திடும் கனமுமில்லை
கோருநீ யண்ட....."

சுண்ணம் என்றால் மிகவும் லேசாகவும் காற்றில் பறக்கக் கூடியதாகவும் இருக்கும்.(கொங்கணவர் 3000)

சுண்ணத்தின் நிறம்

- தவள நிறம்-(சட்டைமுனி நிகண்டு)
- வெண்மை நிறம்(கொங்கணர் வாதகாவியம்)

சுண்ணவகைகளின் தரம்

"ஊதிய சுண்ணம் முசுந்த முதற்றரம்
மாதிய பூநீறு மருவு ரெண்டாந்தரம்
மாதியு பரச மருவு மூன்றாந்தரம்
கோதிய செயநீர் கொடுநாலாம் வித்தையே"

முதற்றரம்- ஊதி எடுக்கின்ற சுண்ணம்
இரண்டாம் தரம்- பூநீறுடன் சேர்த்து செய்யும் சுண்ணம்
மூன்றாம் தரம்- உபரசத்துடன் சேர்த்து செய்யும் சுண்ணம்
நாலாம் தரம்- செயநீருடன் செய்யும் சுண்ணம் (சட்டமுனி நிகண்டு)

❖ சுண்ணம் வெண்மையாக இல்லாமல் கருமையாக இருந்தால் அதை வெண்மையாக மாற்றுவதற்குகான முறை

கல்லுப்புச்சுண்ணத்தை ஒரு தேங்காய் அளவு எடுத்து அதனுடன் கல்லுப்பை ஒரு பலம் சேர்க்க வேண்டும்.சேர்த்த இரண்டு சரக்குகளையும் நன்றாய் அரைத்து சிமிழ் போல் இரண்டு செய்துக்கொள்.இச்சிமிழினுள் கறுப்பேறிய சுண்ணத்தை

வில்லை தட்டி வைத்து மற்றொரு சிமிழால் மூடி குகைக்குள் வைத்து ஊதினால் சுன்னத்தின் கறுப்பு நிறம் அகன்று பஞ்சு போல் வெளுக்கும்.

❖ சுண்ணத்திற்கான சோதனை

.....

பொருத்தவே மஞ்சளதில் போட்டுத்தீரு

ஆடவே ரெத்தம்போல் சிவந்துபோகும்

.....(யாகோபு சுண்ணகாண்டம்)

3.2 SIDDHA ASPECT OF THE DISEASE

நவின்றிடவே யிடுப்புவயிற் பெருத்துக் காணும்

நலமான மேனியது வூதிக் காணும்

குவின்றிடவே மும்மடிப்பு வயிற்றில் தோன்றும்

குணவதியாந் தேவதா பெண்ணா னாலும்

நவின்றிடவே சன்மத்தின் மலடே யாகும்

சதாகாலங் கருப்பமது தரியா தென்று

புவின்றிடவே யூகிமுனி சிகிச்சா சாரம்

புகன்றிட்டார் லோகத்து மாந்தற் காமே.

-யூகி வைத்திய சிந்தாமணி-

பொருள்- உடலில் மற்ற பாகங்களைவிட இடுப்பும் வயிறும் பெருத்திருத்தல், உடல் அதைத்துக் காணல், உந்தியில் மூன்று மடிப்புகள் காணுதல் ஆகிய குறி குணங்களைக் கொண்டு என்றுமே கருத்தரிக்காமலிருக்கும் தன்மைக்கு நிரந்தர மலடு என்று பெயர்.

சூதக நோய் வரும்வழி

.....

தரணியில் பெண்களுக்கு கெற்பநோய்கள்

நயக்கவே வந்து தென்னவென்றால் மைந்தா

நன்மையுடன் ருதுவாகும் நாளிற்றானே

மயக்கவே மாப் பாண்டம் பால் பழத்தினாலே

வந்துதடா சூதகத்தின் வாயு தானே

தானென்ற கருக்குழியில் வாய்வு தங்கி

தளர்ந்த தொரு சோரையினால் தசைதான் மூடி
ஊனென்ற தேகமெல்லாம் மதர்த்து நல்ல
உண்மையுள்ள அடிவயிற்றில் வலி யுண்டாச்சு
பானென்ற கருக்குழிதான் விளக்க மன்றி
பரமான விந்துவங்கே அணுகாதையா
ஏனென்றால் ஆதியிலே வாய்வு கொண்டு
இருந்ததினால் கெற்பமது இல்லை தானே

பொருள்-தரணியில் கற்ப நோய் வருவதற்கு காரணம் என்னவென்றால், ருதுவாகும் நாளில் மாப் பாண்டம், பால். பழவர்க்கம் உண்பதினாலே சூதகவாயு உண்டாகும்.கருக்குழியில் வாயு தங்கி,தசையால் மூடி, அடிவயிற்றில் வலி உண்டாக்கும்.கருக்குழியில் விந்துவை அணுக விடாது.

-அகஸ்த்தியர் அமுத கலை ஞானம்

பொருமிரத்தந்தனை மறித்துப்போதமிகவும் வலியுண்டாங்க
குருதிசேரா வயிறுவலிபோங் கொள்ளுங் கர்ப்பந்தனை யழிக்கும்
வருடி யிடுப்புக் குடைந்துளைக்கும் மலத்தைமிகவும் மிறுக்கி
பெருகப் பனைக்கும் எனப்பெரியோர் பேசுங்கர்ப்பவாயுவிதே

பொருள்-வாயுவானது பொருமி சூதகம் சரிவர வெளிவரவிடாமல் தடுக்கும்.மிகவும் வலியுண்டாகும்.கர்ப்பம் உண்டாகாது.இளம் கர்ப்பத்தை அழித்துவிடும்.இடுப்பு குடைந்து உளையும்.மலத்தை மிகவும் கருக்கி வரளச் செய்யும்.இவை கருப்பவாயுவின் குணங்களாகும்.

-அகத்தியர் ஆயுள்வேதம் 1200

சித்தான கர்ப்பத்தில் சேர்ந்திடும் இரத்தந்தான்
வத்தாம் வுருண்டு வாயுபோல் ஓடிடும்
வற்ற பசிபோகும் உழன்றே இரைந்திடும்
வற்றாக கழிச்சலாம் வன்சூதக வாயுவே.

பொருள்;கர்ப்பக் குழியில் வாயுவுடன் இரத்தமும் சேர்ந்து உருண்டு அங்குமிங்கும் ஓடச் செய்து பசியை அகற்றி கழிச்சலுண்டாகும்.இதற்கு சூதக வாயு என்று பெயர்.

-திருமூலர் கருக்கிடை வயித்தியம் 600

கேளுமே சூதகத்திலக்கினி வாய்வு
கெடுத்துவிடும் மாதவிடாய் கட்டிபோகும்
ஆளுமே கருக்குழியும் தூர்ந்து தேகம்
அப்பனே யுதிரமது அடிமூலத்தில்
நீளுமே சூதகத்தில் வாய்வு தோன்றி
நேரான அடிவயிறு வலிப்புக் காணும்
பாளுமே தலைவலிக்கும் இடுப்பு ளைச்சல்
பக்குவமாய் மருந்துண்ணத் தீருந்தானே

பொருள்-சூதகத்தில் வாயுவும் பித்தமும் குற்றம் அடைந்து மாதவிடாய் கட்டியாகி கருக்குழியும் தூர்ந்து போகும். தலைவலி, இடுப்பு வலி, அடிவயிற்றுவலி ஏற்படும்.மருந்துண்ண குணமாகும்.

-ஆவியளிக்கும் அமுதமுறைச் சுருக்கம்-

இசைந்ததொரு பெண்மலடு எங்குமில்லை
.....னாலே மலடான சேதிகேளு
அசைந்திருக்கும் பேயாலும் பித்தத்தாலும்
அடிவயிறு நொந்துவரும் வாயுவாலும்
பிசைந்தகர்ப்பப் புழுவாலும் கிரகத்தாலும்
பிணியாலும் மேகவை சூரியாலும்
துசங்கெட்டக் கலவியினால் பூவொதுங்கித்
துலங்காமற் பிள்ளையில்லை சொல்லக்கேளே

பொருள்-பித்தத்தாலும்,வாயுவாலும், கர்ப்பப் புழுவாலும், கிரகத்தாலும், வைசூரியாலும் துசங்கெட்டக் கலவியினாலும் பெண்களுக்கு குழந்தையின்மை உண்டாகும்.

-பதினெண் சித்தர்கள் பாடிய வைத்திய சில்லறைக் கோவை-

சூதகக்கட்டி – ருது நீர்க்கட்டி – T.V.Sambasivam pillai

3.3.MODERN ASPECT OF THE DISEASE

PHYSIOLOGY OF FEMALE REPRODUCTIVE SYSTEM

The ovary orchestrates the development and release of a mature oocyte and also elaborates hormones (e.g., estrogen, progesterone, inhibin) that are critical for pubertal development and preparation of the uterus for conception, implantation, and the early stages of pregnancy. To achieve these functions in repeated monthly cycles, the ovary undergoes some of the most dynamic changes of any organ in the body.

Primordial germ cells can be identified by the third week of gestation and their migration to the genital ridge is complete by 6 weeks' gestation. Germ cells can only persist within the genital ridge and are then referred to as *oogonia*. Starting at ~8 weeks' gestation, oogonia begin to enter prophase of the first meiotic division and become primary oocytes. This allows the oocyte to be surrounded by a single layer of flattened granulosa cells to form a primordial follicle.

The oocyte persists in prophase of the first meiotic division until just before ovulation, when meiosis resumes. The quiescent primordial follicles are recruited to further growth and differentiation through a highly regulated process that limits the size of the developing cohort to make sure that folliculogenesis can continue throughout the reproductive life span.

This initial enrollment of primordial follicles to form primary follicles is characterized by growth of the oocyte and the transition from squamous to cuboidal granulosa cells. The theca interna cells that surround the developing follicle begin to form as the primary follicle grows. Acquisition of a zona pellucida by the oocyte and the being there of several layers of surrounding cuboidal granulosa cells mark the development of secondary follicles. It is at this stage that granulosa cells develop follicle-stimulating hormone (FSH), estradiol, and androgen receptors and communicate with one another through the development of gap junction.

Development of a Mature Follicle

The early stages of follicle growth are primarily driven by intraovarian factors, whereas maturation to the state required for ovulation, including the resumption of meiosis in the oocyte, requires the combined stimulus of FSH and luteinizing hormone (LH). Recruitment of secondary follicles from the resting follicle pool requires the direct action of FSH. Accumulation of follicular fluid between the layers of granulosa cells

creates an antrum that divides the granulosa cells into two functionally distinct groups: mural cells that line the follicle wall and cumulus cells that surround the oocyte .

A single dominant follicle emerges from the growing follicle pool within the first 5–7 days after the onset of menses, and the majority of follicles fall off their growth trajectory and become atretic. Autocrine actions of activin and bone morphogenic protein 6 (BMP-6), derived from the granulosa cells, and paracrine actions of GDF-9, BMP-15, and BMP-6, derived from the oocyte, are involved in granulosa cell proliferation and modulation of FSH responsiveness.

Differential exposure to these factors may explain why one follicle is selected for continued growth to the preovulatory stage. The dominant follicle can be distinguished by its size, evidence of granulosa cell proliferation, large number of FSH receptors, high aromatase activity, and elevated concentrations of estradiol and inhibin A in follicular fluid.

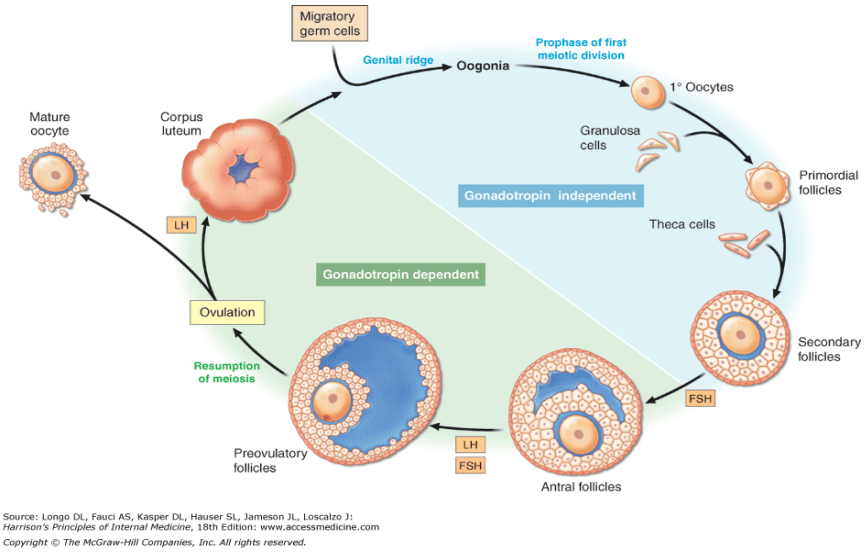


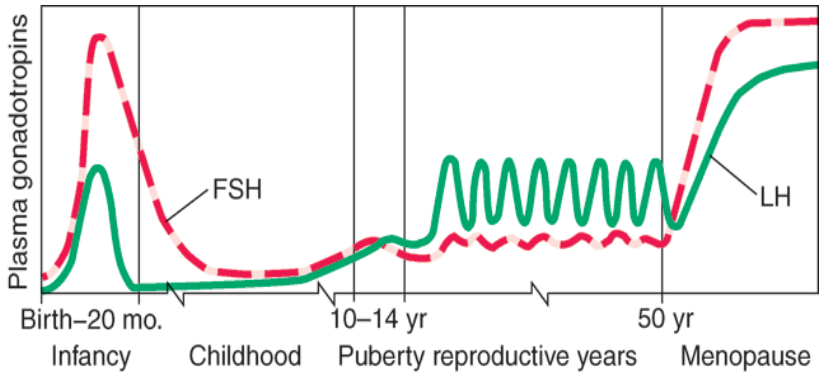
Fig 2.Development of ovarian follicles

Regulation of Ovarian Function

Hypothalamic and Pituitary Secretion

Gonadotropin-releasing hormone (GnRH) neurons develop from epithelial cells outside the central nervous system and migrate, initially alongside the olfactory neurons, to the medial basal hypothalamus. GnRH is secreted into the pituitary portal system in discrete pulses to stimulate synthesis and secretion of LH and FSH from pituitary gonadotropes.

At the onset of puberty, pulsatile GnRH secretion induces pituitary gonadotropin production. In the early stages of puberty, LH and FSH secretion are apparent only during sleep, but as puberty develops, pulsatile gonadotropin secretion occurs throughout the day and night.



Follicle-stimulating hormone (FSH) and luteinizing hormone (LH) are increased during the neonatal years but go through a period of childhood quiescence before increasing again during puberty. Gonadotropin levels are cyclic during the reproductive years and increase dramatically with the loss of negative feedback that accompanies menopause.

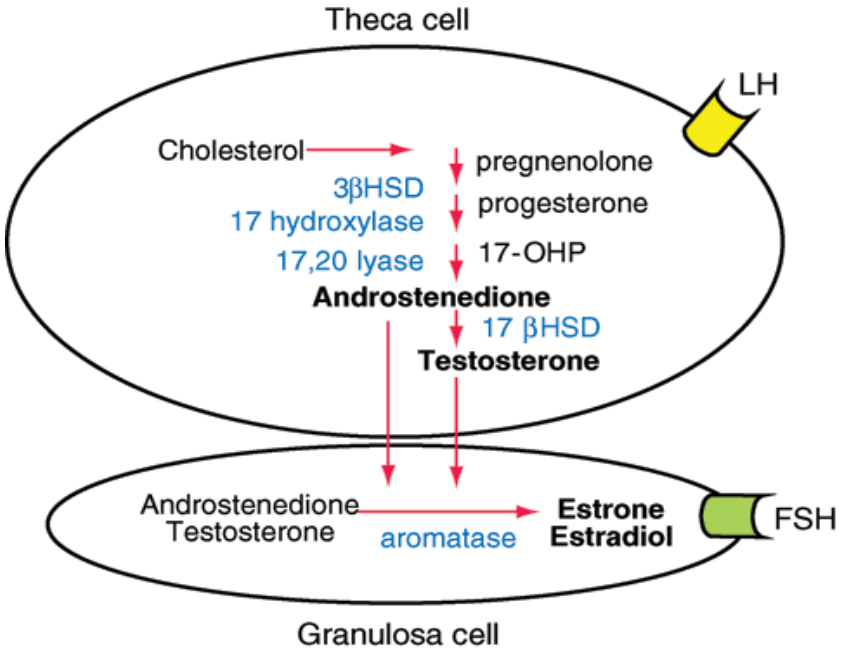
Ovarian steroid

Ovarian steroid–producing cells do not store hormones but produce them in response to LH and FSH during the normal menstrual cycle. The sequence of steps and the enzymes involved in the synthesis of steroid hormones are similar in the ovary, adrenal, and testes. However, the specific enzymes required to catalyze specific steps are compartmentalized and may not be abundant or even present in all cell types.

Within the developing ovarian follicle, estrogen synthesis from cholesterol requires close integration between theca and granulosa cells—sometimes called the *two-cell model for steroidogenesis*. FSH receptors are confined to the granulosa cells, whereas LH receptors are restricted to the theca cells until the late stages of follicular development, when they are also found on granulosa cells. The theca cells surrounding the follicle are highly vascularized and use cholesterol, derived primarily from circulating lipoproteins, as the starting point for the synthesis of androstenedione and testosterone under the control of LH.

Androstenedione and testosterone are transferred across the basal lamina to the granulosa cells, which receive no direct blood supply. The mural granulosa cells are particularly rich in aromatase and, under the control of FSH, produce estradiol, the primary steroid secreted from the follicular phase ovary and the most potent estrogen. Theca cell–produced androstenedione and, to a lesser extent, testosterone are also secreted into peripheral blood, where they can be converted to dihydrotestosterone in skin and to estrogens in adipose tissue. The hilar interstitial cells of the ovary are functionally similar to Leydig cells and are also capable of secreting androgens. **Although stromal cells proliferate in response to androgens [as in polycystic ovarian syndrome (PCOS)], they do not secrete androgens.**

Estrogen production in the ovary requires the cooperative function of the theca and granulosa cells under the control of luteinizing hormone (LH) and follicle-stimulating hormone (FSH). HSD, hydroxysteroid dehydrogenase; OHP, hydroxyprogesterone.



Steroid Hormone Actions

Both estrogen and progesterone play critical roles in the expression of secondary sexual characteristics in women. Estrogen promotes development of the ductile system in the breast, whereas progesterone is responsible for glandular development. In the reproductive tract, estrogens create a receptive environment for fertilization and support

pregnancy and parturition through carefully coordinated changes in the endometrium, thickening of the vaginal mucosa, thinning of the cervical mucus, and uterine growth and contractions.

Progesterone induces secretory activity in the estrogen-primed endometrium, increases the viscosity of cervical mucus, and inhibits uterine contractions. Both gonadal steroids play critical roles in the negative and positive feedback controls of gonadotropin secretion. Progesterone also increases basal body temperature and has therefore been used clinically as a marker of ovulation.

Modulations in binding protein levels by insulin, androgens, and estrogens contribute to high bioavailable testosterone levels in PCOS and to high circulating estrogen and progesterone levels during pregnancy.

Hormonal Integration of the Normal Menstrual Cycle

The sequence of changes responsible for mature reproductive function is coordinated through a series of negative and positive feedback loops that alter pulsatile GnRH secretion, the pituitary response to GnRH, and the relative secretion of LH and FSH from the gonadotrope.

For the majority of the cycle, the reproductive functions in a classic endocrine negative feedback mode. Estradiol and progesterone inhibit GnRH secretion, and the inhibins act at the pituitary to selectively inhibit FSH synthesis and secretion. This negative feedback control of FSH is critical to development of the single mature oocyte that characterizes normal reproductive function in women.

In addition to these negative feedback controls, the menstrual cycle is uniquely dependent on estrogen-induced positive feedback to produce an LH surge that is essential for ovulation of a mature follicle. The neural signaling pathways that distinguish estrogen negative versus positive feedback are incompletely understood.

The Follicular Phase

This phase is characterized by recruitment of a cohort of secondary follicles and the ultimate selection of a dominant preovulatory follicle .The follicular phase begins, by convention, on the first day of menses. follicular recruitment is initiated by the rise in FSH

Increasing levels of estradiol are answerable for proliferative changes in the endometrium. The exponential rise in estradiol results in positive feedback on the pituitary, leading to the generation of an LH surge (and a smaller FSH surge), thereby triggering ovulation and luteinization of the granulosa cells.

The Luteal Phase

This phase begins with the formation of the corpus luteum from the ruptured follicle in response to ovulation signals. Progesterone and inhibin A are produced from the luteinized granulosa cells, which continue to aromatize theca-derived androgen precursors, producing estradiol. The combined actions of estrogen and progesterone are responsible for the secretory changes in the endometrium that are necessary for implantation.

Clinical Assessment of Ovarian Function

Menstrual bleeding should become regular within 2 to 4 years of menarche, although anovulatory and irregular cycles are common before that. For the remainder of adult reproductive life, the cycle length counted from the first day of menses to the first day of subsequent menses, is ~28 days, with a range of 25–35 days. However, cycle-to-cycle variability for an individual woman is ± 2 days.

Luteal phase length is relatively constant between 12 and 14 days in normal cycles; thus, the major variability in cycle length is due to variations in the follicular phase. The duration of menstrual bleeding in ovulatory cycles varies between 4 and 6 days. There is a gradual shortening of cycle length with age such that women over the age of 35 have cycles that are shorter than during their younger reproductive years. Anovulatory cycles increase as women approach the menopause, and bleeding patterns may be erratic.(HARRISON'S principles of INTERNAL MEDICINE)

POLYCYSTIC OVARIAN SYNDROME

Introduction

The polycystic ovary syndrome was characterized by symptoms of excessive androgenisation, such as hirsutism and acne, and obesity in addition to infertility in the presence of bilateral polycystic ovaries (PCO). These ovaries were described as being enlarged,having a markedly thickened tunica albuginea with hyperplasia of the theca interna cells.(Gautam N *et al*;2007)

Stein-Leventhal syndrome, the association of amenorrhea with bilateral polycystic ovaries and obesity was first described in 1935 by Stein and Leventhal. Its complex genetic origins are likely polygenic and/or multifactorial.

Pathogenesis

Polycystic Ovaries develop when the ovaries are stimulated to produce excessive amounts of male hormones (androgens), particularly testosterone, either through the release of excessive luteinizing hormone (LH) by the anterior pituitary gland or through high levels of insulin in the blood (hyperinsulinaemia) in women whose ovaries are sensitive to this stimulus.

The syndrome acquired its most widely used name due to the common sign on ultrasound examination of multiple (poly) ovarian cysts. These "cysts" are actually immature follicles, not cysts ("polyfollicular ovary syndrome" would have been a better name). The follicles have developed from primordial follicles, but the development has stopped ("arrested") at an early antral stage due to the disturbed ovarian function. The follicles may be oriented along the ovarian periphery, appearing as a 'string of pearls' on ultrasound examination. A majority of patients with PCOS have insulin resistance and/or are obese. Their elevated insulin levels contribute to or cause the abnormalities seen in the hypothalamic-pituitary-ovarian axis that lead to PCOS.

Aromatase is an enzyme that converts androstenedione to estrone and testosterone to estradiol and this is found in adipose tissue. The excess of adipose tissue in obese patients creates the paradox of having both excess androgens (which are responsible for hirsutism and virilization) and estrogens. The development of PCOS is described by all these steps; LH over FSH dominance, increased ovarian androgen production,

hyperinsulinemia increases GnRH pulse frequency, decreased SHBG binding and decreased follicular maturation. Insulin resistance is a common finding among patients of normal weight as well as those overweight patients. PCOS may be found with chronic inflammation, several investigators correlating inflammatory mediators, anovulation and with other PCOS symptoms. The risk of PCOS development was shown to be higher in lesbian women than in heterosexuals.

Symptomatic presentation of the polycystic ovary syndrome

- Obesity

The occurrence of obesity in PCOS is relatively common, with more than 50% being overweight (BMI >25kg/m2 or obese (BMI >27kg/m2). The weight distribution is classically with a central deposition of fat in the truncal region and manifest in an increased waist/hip ratio.

- Acne

Acne is an inflammatory disorder of the hair follicle and its associated sebaceous and apocrine gland. It is present in up to one third of the women with PCOS.

- Hirsutism

Hirsutism is the growth of terminal hair on the body of a women, in the same pattern as in an adult male. The cause of hirsutism is androgen action upto the hair follicle.

- Androgenic alopecia

Androgenic is a progressive pattern of hair loss of scalp terminal hair, which is a common finding in men

- Acanthosis nigricans

Acanthosis nigricans is a mucocutaneous eruption that occurs most frequently in the axillae, skin flexures and the nape of the neck. It is manifest by increased pigmentation and papillomatosis.

Diagnostic Criteria

Diagnostic criteria have been established by the modified consensus of the National Institutes of Health and Child Health and Human Development (1990) and by consensus criteria established during the ESHRE/Rotterdam Conference in 2003

NIH Criteria (both required)

1. Chronic anovulation
2. Clinical or biochemical signs of hyperandrogenism

Minor NIH Criteria

1. Insulin resistance
2. Perimenarchal onset of hirsutism and obesity
3. Elevated LH/FSH ratio
4. Intermittent anovulation associated with hyperandrogenemia
5. Ultrasound evidence of polycystic ovaries

Rotterdam Criteria-two of three required

1. Oligo and /or anovulation
2. Clinical or biochemical signs of hyperandrogenism
3. Polycystic ovaries

Differential diagnosis

Other causes of irregular or absent menstruation and hirsutism, such as congenital adrenal hyperplasia, Cushing's syndrome, hyperprolactinemia, androgen secreting neoplasms, and other pituitary or adrenal disorders, should be investigated. PCOS has been reported in other insulin resistant situations such as acromegaly.

Long-Term risks of PCOS

Endometrial carcinoma-ovarian carcinoma: In chronic anovulatory patients with PCOS, persistent estrogen stimulation, unopposed by progesterone, increases the risk of

endometrial carcinoma. Additionally, a hyperestrogenic state in PCOS is associated with an increased risk of breast cancer as well as a two to threefold increase in ovarian cancer(Catherine J). The incidence of insulin resistance in PCOS women is 25%-70% .In women with PCOS, the rate of early pregnancy loss has been reported to be as high as 40%.The early pregnancy loss rate in women with PCOS has been attributed to elevated LH concentrations, Higher androgen levels, insulin resistance and obesity.

Cardiovascular disease-hypertension, an unfavorable lipid profile, and reduced endothelial elasticity are all more common in obese women with PCOS. (Sabaratnam Arulkumaran Lesley Regan)

Radiologic Studies in PCOS

Ultra sonographic examination of PCOS women reveals an increase in ovarian size and an increased number of immature follicles. The Rotterdam criteria include enlarged ovaries measuring >10 cm3 and more than 12 follicles measuring 2-9 mm in diameter.PCOS is a disorder comprising multiple clinical variants and apparent genetic propensities grouped together into the "PCOS phenotype" (Catherine J *et al*)

Epidemiology

PCOS is the commonest endocrine disorder in women of reproductive age and an estimated prevalence of 5-10% in this age group. By contrast, 23% of asymptomatic women will have the ultrasound finding of polycystic ovarian morphology(Poison et al.1988).

4. MATERIALS AND METHODS

4.1 PREPARATION OF NAVACHARA CHUNNAM

The trial drug *Navaachara Chunnam* was formulated based on the 'Anuboga Vaithya Navaneetham'. The ingredients are *Navacharam*, juice of *Oomathai (Datura innoxia)*. The raw material was obtained from country drug shop, Chennai and the plant was collected from in and around Chennai. Both materials were identified and authenticated by the botanist and the experts of *Gunapadam* (Pharmacology) at Govt Siddha Medical College, Arumbakkam, Chennai. After identification, the samples of raw materials have been preserved in the laboratory of the department for future reference.

Purification

Dissolve the *Navacharam* in hot water. Filter the solution and cool it to room temperature. Then place the solution in a vessel in the sunlight. The solution turns into salt due to sunlight. Collect the purified salt.

Preparation of Chunnam:

Materials Required :

- *Navacharam* 35g
- *Datura innoxia* leaf juice 1.3 litre
- *Datura innoxia* leaves

Procedure

Place the Purified *Navacharam* on a sand plate and heat up with Datura leaf juice(*Surukku koduththal*). Then grind the leaves of datura and make a *kavasam* of thickness 0.5 inch for the *Navacharam*. Dry the *kavasam*. Grind the limestone using Datura leaf juice and make a moosai and lid. Place the dried *kavasam* within this *moosai* and close it with lid and seal it with sanded cloth five times .Dry it and Put the *Pudam* with dung cakes of weight six times the *kavasam*. After finishing the *pudam* let the *moosai* undisturbed to give away the heat. Finally Chunnam is prepared.

Storage:

The drug *Navachara Chunnam* was stored in a clean air tight container.

Dosage: 260 mg – two times a day

Form of medicine: *Chunnam*

Route: Enteral

Vehicle: *Soembu kudineer*

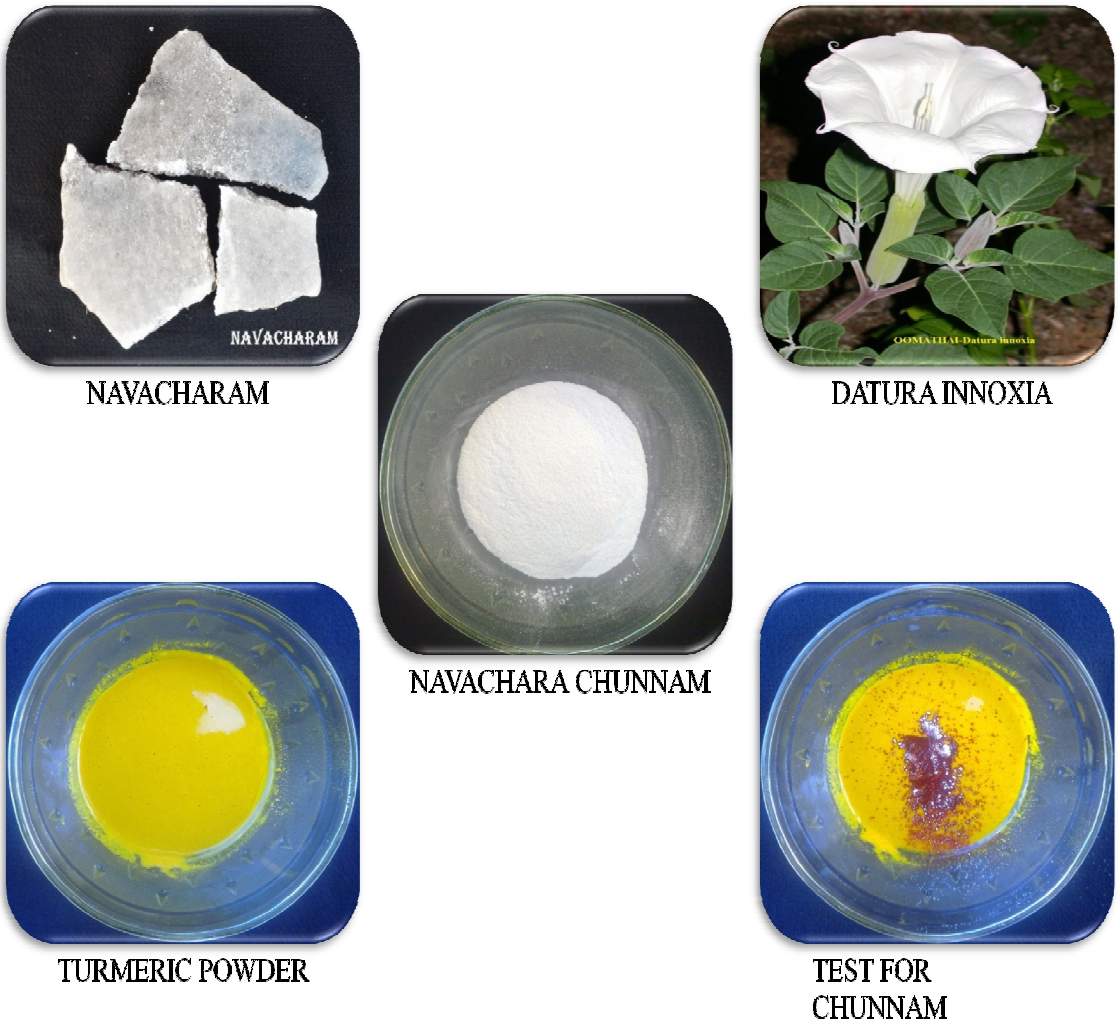


Fig.No.3 NAVACHARA CHUNNAM

ANALYSIS AS PER CLASSICAL LITERATURE

- **Reaction with turmeric***:* According to the Siddha Pharmacopoeia, *"Chunnam* become red when turmeric powder is added to it because of the presence of Lime in it (calcium)". Addition of small quantity of turmeric powder with water and prepared *Navachara Chunnam* turned white colour to red which confirmed that the preparation was perfect and complete.

- **Floating on Water**: If the *Chunnam* is well prepared, it floats on water. A small amount of *Navachara Chunnam* was sprinkled over the water in a glass container. It was found that the *Chunnam* particles floated over the surface of water indicated lightness of the trial drug.

- **Lines on fingers:** *Chunnam* in well prepared form should be fine. When taken between thumb and forefinger, the fine powder will fill the lines of the fingerprint. A pinch of *Chunnam* was taken in between the thumb and index finger and rubbed. It was observed that the *Navachara Chunnam* entered into the lines of the finger, and was not easily washed out from the cleavage of the lines confirmed its fineness.

- **Lustre:** If any shining or sparkly particles present in *Chunnam*, it indicates that the drug is not prepared properly and contains unchanged substances like metals and other toxic substances. There should be no shining and sparkling particles present in the well prepared *Chunnam*. The *Navachara Chunnam* was taken in a Petri dish and observed for any lustre in daylight through magnifying glass. No lustre was observed in the *Chunnam*.

- **Taste**: The well prepared *Chunnam* should be completely tasteless. Presence of any taste like sweet, sour or bitter indicate incomplete preparation which required another calcination process. When a small amount of *Navach Chunnam* was kept on the tip of the tongue, no specific taste was observed rather than a mild irritation due to its alkaline nature.

  The finished product, *Navachara Chunnam* was analysed for quality control as above based on the classical Siddha literature and found suitable for further studies

4.2. STANDARDIZATION OF *NAVACHARA CHUNNAM:*

Standardization of drugs helps to confirm its identity and determination of its quality, effectiveness .Standardization of herbo mineral drug is based on qualitative and quantitative analysis through physico-chemical properties and instrumental studies. The physico-chemical analysis and elemental analysis of this herbomineral formulation have been done at SCRI (Siddha Central Research Institute) and Anna university (FTIR in Dept. of Chemistry and SEM in Dept. of Mechanics)

4.2.1 Physico-Chemical Investagations:

Physico-chemical studies like Total ash, Water soluble ash, and Acid Insoluble ash, Loss on drying at 105°C and pH have been done at Siddha Central Research Institute as per the guide lines of WHO.

Determination of Total Ash:

Incinerate about 2 to 3 g accurately weighed, of the ground drug in a tared platinum or silica dish at a temperature not exceeding 450º until free from carbon, cool and weigh. Calculate the percentage of ash with reference to the air-dried drug.

Determination of Acid Insoluble Ash:

Boil the ash obtained for 5 minutes with 25 ml of dilute hydrochloric acid; collect the insoluble matter in a Gooch crucible or on an ash-less filter paper, wash with hot water and ignite to constant weight. Calculate the percentage of acid-insoluble ash with reference to the air dried drug.

Determination of Moisture Content (Loss on Drying):

Procedure set forth here determines the amount of volatile matter (i.e., water drying off from the drug). For substances appearing to contain water as the only volatile constituent, the procedure given below, is appropriately used. Place about 10 g of drug (without preliminary drying) after accurately weighing (accurately weighed to within 0.01 g) it in a tared evaporating dish. For example, for underground or un powdered drug, prepare about 10 g of the sample by cutting shredding so that the parts are about 3 mm in thickness.

After placing the above said amount of the drug in the tared evaporating dish dry at 105º for 5 hours, and weigh. Continue the drying and weighing at one hour interval until difference between two successive weighing corresponds to not more than 0.25 per cent. Constant weight is reached when two consecutive weighing after drying for 30 minutes and cooling for 30 minutes in a desiccator, show not more than 0.01 g difference.

Determination of pH:

1% solution of plant drug was prepared in distilled water and pH was determined using pH meter SYSTRONICS DIGITAL pH METER, MK VI.

4.2.2 Preliminary Chemical Analysis

Preparation of Extract :

Add 5 gm of the sample to 50ml of distilled water. Boil the solution for 20 minutes, cool and then filter. Use the Extract for the following tests.

S.No	Experiment	Observation	Inference
1.	**Test for reducing Sugar :** To 5ml of Benedicts qualitative reagent, add 10 drops of extract, then boil for two minutes	Green / yellow / red precipitate	Presence of Reducing Sugar
2.	**Test for Starch :** To 5 ml of extract add 2ml of acetic acid and then add few drops of N/50 Iodine Solution.	Blue colour	Presence of Starch
3.	**Test for Proteins :** To 2 ml of extract, add 2ml of 5% Sodium Hydroxide mix and add 2 drops of Copper Sulphate Solution.	Violet or purple colour	Presence of Proteins
4.	**Test for amino Acid :** Place 2 drops of extract on a filter paper and allow to dry well. Then spray 1% ninhydrin over the same and allow to dry.	Violet colour	Presence of Amino Acid
5.	**Test for Albumin :** To 2 ml of extract, add 2ml of Esboch's reagent.	Yellow precipitate	Presence of Albumin
6.	**Test for Phosphate :** To 2ml of extract, add 2ml of ammonium Molybdate solution and 2ml of concentrated Nitric Acid.	Yellow precipitate	Presence of Phosphate

7.	**Test for Sulphate :** To 2 ml of extract add 2ml of 4% ammonium oxalate solution.	White precipitate	Presence of Sulphate
8.	**Test for Chloride :** Add 2ml of extract to dilute nitric acid till the effervescence ceases. Then add 2 ml of Silver Nitrate Solution.	Cloudy white precipitate	Presence of Chloride
9.	**Test for Iron :** To 2ml of extract, add 2ml of ammonium thio cynate solution and add 2ml of concentrated Nitric Acid.	Red colour	Presence of Iron
10.	**Test for Calcium :** To 2 ml of extract, add 2 ml of 4% ammonium Oxalate Solution.	White precipitate	Presence of Calcium
11.	**Test for Sodium :** Make a paste with 2 pinches of the sample with HCl and Introduce it into the blue flame.	Yellow flame	Presence of Sodium
12.	**Test for Potassium :** Add a pinch of the sample to 2 ml of Sodium Nitrate Solution. Then add 2ml of Cobal Nitrate in 20% acetic acid.	Yellow precipitate	Presence of Potassium
13.	**Test for Zinc :** To 2ml of extract, add few drops of Sodium Hydroxide.	White precipitate	Presence of Zinc
14.	**Test for Magnesium :** To 2ml of extract, add few drops of Sodium Hydroxide Solution	White precipitate	Presence of Magnesium
15.	**Test for Alkaloids :** To 2ml of extract, add 2ml of Potassium Iodide Solution To 2ml of extract add 2ml of Picric Acid. To 2 ml of extract add 2ml of Phosphotunqstic Acid.	Red colour Yellow colour White precipitate	Presence of Alkaloids Presence of Alkaloids Presence of Alkaloids
16.	**Test for Tannic Acid :** To 2ml of extract add 2 ml of Ferric Chloride Solution	Black precipitate	Presence of Tannic Acid

4.3. ACUTE AND SUB ACUTE TOXICITY STUDY ON NAVACHARA CHUNNAM

Animals

Mice of either sex weighing 25-30g and rats weighing 210-240g were obtained from the animal house of Vels University. The animals were used with the approval of the Institute animal ethics committee and obtained from Vels University, Chennai. They were fed with a balanced standard pellet diet and maintained under standard laboratory conditions, providing 24-28^{0}C temperature, standard light cycle (12 h light, 12 h dark) and water ad libitum. Animals were kept in cages with raised floors of wide mesh to prevent coprophagy. Animal welfare guidelines were observed during the maintenance period and experimentation. The rats were randomly assigned to control and different treatment groups, six animals per group. The animals were acclimatized for one week under laboratory conditions.

ACUTE TOXICITY STUDY-OECD 425 GUIDELINES

Acute oral toxicity test for the *Navachara Chunnam* was carried out as per OECD Guidelines 425. As with other sequential test designs, care was taken to ensure that animals are available in the appropriate size and age range for the entire study. The test substance is administered in a single dose by gavage using a stomach tube or a suitable intubation cannula. The fasted body weight of each animal is determined and the dose is calculated according to the body weight. After the substance has been administered, food was withheld for a further 2 hours in mice. The animals were observed continuously for the first 4 h and then each hour for the next 24 h and at 6 hourly intervals for the following 48 h after administering of the test drug, to observe any death or changes in general behaviour and other physiological activities. Single animals are dosed in sequence usually at 48 h intervals. However, the time interval between dosing is determined by the onset, duration, and severity of toxic signs. Treatment of an animal at the next dose was delayed until one is confident of survival of the previously dosed animal.

Observation of toxicity signs:

General behavior, respiratory pattern, cardiovascular signs, motor activities, reflexes, change in skin and fur, mortality and the body weight changes were monitored daily. The time of onset, intensity, and duration of these signs, if any, was recorded.

SUB-ACUTE TOXICITY

In a 28-days sub acute toxicity study, twenty four either sex rats were divided into four groups of 6 rats each. Group I that served as normal control was administered with distilled water (p.o.) while groups II, III and IV were administered daily with the *Navachara Chunnam* (p.o.) for 28 days at a dose of 25, 50 and 100mg/kg respectively. The animals were then observed daily for gross behavioral changes and any other signs of subacute toxicity. The weight of each rat was recorded on day 0 and weekly throughout the course of the study, food and water consumption per rat was calculated. At the end of the 28 days they were fasted overnight, each animal was anaesthetized with diethyl ether, following which they were then dissected and blood samples were obtained by cardiac puncture into heparinised tubes. The blood sample collected from each rat was centrifuged with 3000 X g at $4^{o}C$ for 10 min to separate the serum and used for the biochemical assays.

Hematological and blood biochemical analyses:

At the end of the study, all animals were kept fasted for 16-18 h and then anesthetized with anesthetic ether on the 28th day. Blood samples for hematological and blood chemical analyses were taken from retro orbital vein. Heparinized blood samples were taken for determining complete blood count (white blood cell count, differential white blood cell count, platelet count, red blood cell count, hematocrit, and hemoglobin) by semiautomated hematology analyzer. The serum from non-heparinized blood was carefully collected for blood chemistry and enzyme analysis (glucose, creatinine, total protein, albumin, total and direct bilirubin, serum glutamate-oxaloacetate transaminase (SGOT), serum glutamate pyruvate transaminase (SGPT), and alkaline phosphatase (ALP)) were automatically determined using autoanalyzer.

Necropsy:

All rats were sacrificed after the blood collection. The positions, shapes, sizes and colors of internal organs were evaluated. The Spleen, Testes, Pancreas, Lung, Liver, Brain, Heart, Stomach, Intestine, Bone, Ovary, and Kidney tissues were excised from all rats to visually detect gross lesions, and weighed to determine relative organs' weights and preserved in 10% neutral formalin for histopathological assessment. The tissues were embedded in paraffin, and then sectioned, stained with haematoxylin and eosin and were examined microscopically.

Statistical analysis

Values were represented as mean ± SEM. Data were analyzed using one-way analysis of variance (ANOVA) and group means were compared using the Tukey-Kramer Multiple Comparison test using GraphPad Instat-V3 software. P values < 0.05 were considered significant.

4.4 EVALUATION OF OVULOGENIC EFFECT OF NAVACHARA CHUNNAM IN RATS

Animal Selection

Mice of either sex of wistar strain weighing 28-32gms and Female albino rats of wistar strain weighing about 95–135 gm were used. Pregnant animals were excluded. Animals were fed on conventional diets and water *ad libitum* and they were maintained under standard conditions of humidity, temperature (20- 24°C) and light (12 h light: 12 h dark cycle). Animals were kept in polycarbonate cages with laced steel roofs. The animals were acclimatized for one week under laboratory conditions. The study was conducted at the Vel's University, Chennai after obtaining Institutional Animals Ethical Committee clearance bearing the number XIII/VELS/PCOL/57/2000/CPCSEA/ IAEC/08.08.2012.

Drug and stock solution

The *Navachara Chunnam* was accurately weighed using electronic balance and suspended in 2% carboxy methyl cellulose solution to so as to get 200mg/kg of main stock solution and this was used in this study. All the chemicals and standard drugs were procured from authorized suppliers.

Acute toxicity study:

Acute oral toxicity test was carried out as per OECD Guidelines 425 up and down method. Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 h, and daily thereafter, for a total of 14 days. Initially starting at a dose of 2000 mg/kg of *Navachara Chunnam* was given. Body weight and behavioral changes were noted. Animals are observed individually and were systematically recorded. The acute toxicity was occurred at 250mg/kg after 48 hours of oral drug treatment. Hence, one-tenth and one fifth dose was selected as therapeutic dose from maximum tolerable dose for further pharmacological study.

Ovulation stimulation activity:

In the present study, twenty four Virgin female wistar rats weighing of around (88- 130 gm) of 2 month old were obtained from the animal house at Vel's University, Chennai. Before starting drug treatment, the reproductive cycles of the rats were synchronized by the following method. 100µg estradiol dissolved in 2 ml olive oil was injected subcutaneously. All rats after a 24 hr period, received intramuscular injections of 50 µg progesterone dissolved in olive oil. After few hours, Vaginal smears were obtained by vaginal lavage to monitor ovulation and oestrous cycle. Vaginal smears were prepared by washing vaginal opening with 0.9% w/v of sodium chloride with a glass dropper and placed in a clean glass slide and viewed under light microscope at 40X magnification. Examination of vaginal smears showed that all the animals were in the estrous stage. All the animals were weighed daily after drug administration for 10 days. The suitable sensitive rats were divided into four groups of six each as follows:

- Group I Normal Control animals given only 2ml/kg of CMC solution.
- Group II animals were administered 25 mg/kg of *Navachara Chunnam* for 10days,
- Group III rats were received 50mg/kg of *Navachara Chunnam* for 10 days
- Group IV received clomiphene 10mg/kg and served as standard. All the drugs were given orally.

2ml of blood was collected by retro orbital puncture. Blood samples were centrifuged for 15 minutes at 4000 rpm and the separated serum samples were frozen at -20°C and kept for later estimation of LH, FSH and estradiol by ELISA method. At the end of experiment, the animals were sacrificed using ether anesthesia and the uteri were

removed and weight was recorded. The oviduct was dissected out from the rats, suspended in normal saline and placed on a microscopic slide with a cover slip to count the number of ova analysis.

Histological analysis

At the end of the treatment, the ovary was removed and placed in formalin fixative for 20-24 hours. Fixed tissue samples were placed in ascending concentrations of alcohol and embedded in paraffin. Slices of tissue, 5-7 μm thick, were prepared and stained with hematoxylin and eosin, and then monitored and evaluated with a light microscope. To study folliculogenesis all tissue blocks were serially sliced. Follicle identification was based on the detection of a nucleus. The numbers of follicles (primordial, primary, etc.) were counted. Follicle recognition criterion on the slides was based on the type of epithelial cells surrounding them. For example, primordial follicles have squamulose cells whereas primary follicles are surrounded by cuboidal cells. The numbers of follicles per slide were randomly counted.

Statistical analysis

Statistical significance of data was assessed by analysis of variance (one-way ANOVA) followed by a comparison between different groups using Dunnet test.

4.5. CLINICAL ASSESSMENT:

Siddha system had been survived through centuries and cannot be lightly condemned as being unscientific. This ancient system offers simple, cost effective and nature friendly therapy. Special interest had laid on women's health since status of women is an index of the community. Nowadays change in lifestyle, food habits and stress women tend to develop polycystic ovarian syndrome due to hormonal imbalance with ovulation disorder. So *Navachara chunnam* was focused to trial for remedy of PCOS (*Sudhagakatti).*

Objectives

To explore the efficacy of *Navachara chunnam* in women with Polycystic ovarian syndrome.

Study Design

The Open clinical trial – Phase II B

Study Centre

Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Arumbakkam, Chennai – 106.

Study Participants

Women members of all races and ethnic groups are eligible for this trial. Treatment administered on an outpatient and inpatient basis. The patients selected from Out-patient and In-patient department of Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Chennai – 106.

Number of Subjects

No of participants 44

Registration Process

To register a patient, the following documents should be completed by the investigator.

- Copy of required laboratory tests
- Signed patient consent form
- Other appropriate forms (e.g., Trial Pro forma)

The investigator verified eligibility and assigned a patient study number, drug dose and register the patient on the study.

Inclusion criteria

44 women with PCOS, ages between 16-38 year were selected for open label clinical trial by using Rotterdam Criteria

Rotterdam Criteria-two of three required

- Oligo and /or anovulation
- Clinical or biochemical signs of hyperandrogenism
- Polycystic ovaries

Exclusion criteria

- Cushing syndrome
- Late-onset 21-hydroxylase deficiency
- Thyroid dysfunction
- Androgen secreting tumours

  Before and at the end of study, the following investigations were carried out;
- Assessment of menstrual history(Regularity of the cycle, Length of the cycle, Duration of menstruation, Level of blood flow)
- Physical examination for body weight, BMI, waist/hip ratio and Blood pressure.
- Laboratory investigation for Hormonal assay (LH, FSH, Free testosterone, 17-hydroxyprogesterone, estradiol, insulin (fasting and post prandial) and lipid profile.
- USG pelvis
- Follicular Study

Each woman was asked to report any side-effect during the treatment. Safety parameter (hematology, liver and renal function, serum electrolytes and uric acid) were assessed before and at 2 month intervals during the study.

All subjects gave their informed consent before entering the study.

Withdrawal Criteria

Patients were removed from study when any of the criteria listed below applied. The reason for study removal and the date of removal of patient had been documented in the Case Report Form.

- Irregular medication.
- Patients who are all not cooperating to take blood samples.
- Any adverse reactions during the study period.

- Patient decides to withdraw from the study, or
- Unwanted prolonged illness during the study period.

Evaluation of Clinical Parameters

Patients are clinically evaluated by the following parameters:

History Taking

Age, occupation, socio economic status, complaints and its duration, menstrual history, marital history. History of parity, family history, previous illness, and personal habits were recorded in the case sheet for every patient at the time of first visit to the OP.

Investigations

All the patients were subjected to the laboratory investigations before and after the treatment.

Blood: Complete haemogram, Blood sugar fasting & post prandial, Blood urea, Serum creatinine, Serum cholesterol and hormonal assay.

Urine: Albumin,Sugar,Deposits,

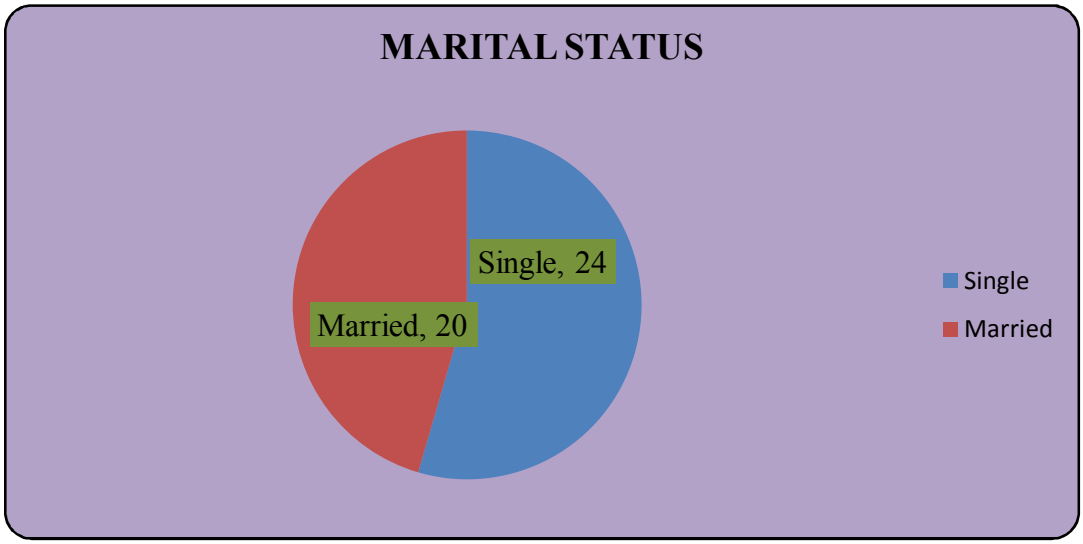
Ultrasound Sono Gram: Whole Abdomen and Pelvis.

Criteria for Assessment of Response to Therapy:

1. Marked response : 90% relief in signs and symptoms and improvement in lab investigations.
2. Moderate response : 70 - 80 % relief in the presenting signs and symptoms and improvement in lab investigations.
3. Mild response : 60-70% relief signs and symptoms.
4. Poor response : 50% relief of signs and symptoms no marked changes

Table No.1- (MARITAL STATUS)

SL. NO	Marital Status	NO. OF PATIENTS	PERCENTAGE (%)
1.	Single	24	55
2.	Married	20	45
TOTAL		44	100



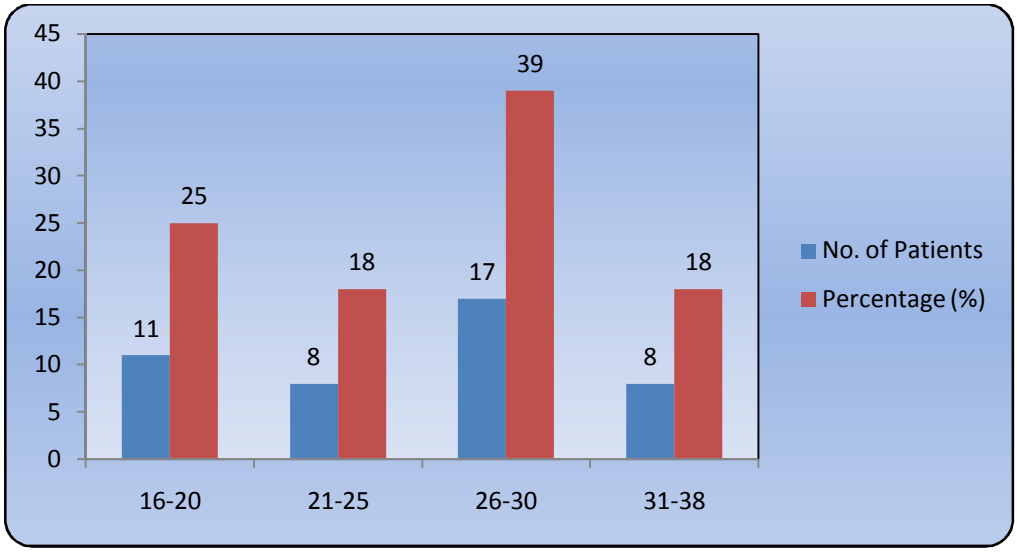
Inference:

Out of 44 patients 20 (45%) are married

Out of 44 patients 24 (55%) are Single.

Table No.2-(AGE DISTRIBUTION)

SL. NO	AGE IN YEARS	NO. OF PATIENTS	PERCENTAGE (%)
1.	16-20	11	25
2.	21-25	8	18
3.	26-30	17	39
4.	31-38	8	18
TOTAL		44	100



Inference:

Among 44 patients,

- 11 patients belongs to the age group of 16-20 years
- 8 patients belongs to the age group of 21-25 years
- 17 patients belongs to the age group of 26-30 years
- 8 patients belongs to the age group of 31-38 years

CLINICAL STUDY ON *NAVACHARA CHUNNAM* FOR PCOS

Sl.No.	O.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
1.	7349	DIANA	27/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,weight gain present	18.06.2012 to 20.08.2012	Marked
2.	3517	KALAIMAGAL	20/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Acanthosis nigricans, hirsutism present	09.07.2012 to 08.09.2012	Marked
3.	3182	VALARMATHI	16/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	07.07.2012 to 17.102012	Marked
4.	7464	UMAMAHESWARI	37/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation, Infertility present	24.07.2012 to 28.09.2012	Marked
5.	4189	RAJESWARI	27/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation, hirsutism present	21.08.2012 to 01.11.2012	Moderate
6.	2396	NITHYA	19/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	13.08.2012 to 13.11.2012	Marked
7.	4283	DEEPAPRIYA	17/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, weight gain present	21.08.2012 to 18.11.2012	Marked
8.	5245	SUGANYA	26/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	25.08.2012 to 22.11.2012	Marked
9.	6482	NIRMALA	27/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,Infertility present	31.08.2012 to 28.11.2012	Moderate
10.	7146	PARVATHY	26/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	05.09.2012 to 3.12.2012	Marked

CLINICAL STUDY ON *NAVACHARA CHUNNAM* FOR PCOS

Sl.No.	O.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
11.	7908	DHANALAKSHMI	30/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,Infertility present	06.09.2012 to 07.12.2012	Moderate
12.	8767	KALADEVI	32/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation, Infertility present	10.09.2012 to 11.12.2012	Marked
13.	8827	PRIYANKA	20/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation, weight gain present	10.09.2012 to 09.12.2012	Marked
14.	9110	KRISHNAKUMARI	27/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	11.09.2012 to 12.12.2012	Moderate
15.	168	SRIVALLI	38/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	15.09.2012 to 17.12.2012	Marked
16.	1221	KARPAGAM	30/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	20.09.2012 to 23.12.2012	Marked
17.	1371	ANITHA	29/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	21.09.2012 to 24.12.2012	Marked
18.	5201	DIVYA	20/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, weight gain present	06.10.2012 to 02.01.2013	Mild
19.	8395	SARALA	33/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Infertility Constipation present	20.10.2012 to 04.01.20113	Marked
20.	8825	CAROLIN MERY	30/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	23.10.2012 to 30.12.2012	Marked

21.	7710	VASANTHI	28/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	17.10.2012 to 29.12.2012	Moderate
22.	6619	FATHIMA	24/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	12.10.2012 to 31.12.2012	Marked
23.	7779	AMUL	30/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	17.10.2012 to 28.12.2012	Marked
24.	8005	LATHA	22/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	18.10.2012 to 02.01.2013	Poor
25.	9657	DHANALAKSHMI	25/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	27.10.2012 to 03.01.2013	Marked
26.	341	RADHA	26/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	31.10.2012 to 30.12.2012	Marked
27.	1001	ARUNA	27/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	03.11.2012 to 04.01.2013	Mild
28.	1672	MEENALOKSINI	26/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	06.11.2012 to 29.12 2012	Marked
29.	1523	AMBIKA	17/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	06.11.2012 to 02.01.2013	Marked
30.	1558	PIRAMILA	30/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	06.11.2012 to 04.01.2013	Moderate

CLINICAL STUDY ON *NAVACHARA CHUNNAM* FOR PCOS

Sl.No.	O.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
31.	1528	SUGANYA	17/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	06.11.2012 to 28.12.2012	Marked
32.	1755	POWLIN SHANTHA	23/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,Acanthosis nigricans present	07.11.2012 to 02.01.2013	Marked
33.	1761	REJESWARI	31/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	07.11.2012 to 31.12.2012	Poor
34.	2082	SUBHASINI	35/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	08.11.2012 to 03.01.2013	Moderate
35.	2288	SARASWATHY	23/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	09.11.2012 to 31.12.2012	Marked
36.	2562	RADHIGA	25/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	10.112012 to 03.01.2013	Moderate
37.	2286	SOWMIYA	28/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation, hirsutism present	09.11.2012 to 04.01.2013	Marked
38.	2564	AISHWARYA	21/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	10.11.2012 to 29.12.2012	Poor
39.	2566	KAVYA	20/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,Weight gain present	10.11.2012 to 30.12.2012	Mild
40.	2557	DEEPA	31/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,infertility present	10.11.2012 to 02.01.2013	Marked

Sl.No.	I.P. No.	Name	Age/ Sex	Symptoms	Duration	Results
41.	664/6045	SUGANYA	19/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation, weight gain present	12.06.2012 to 28.06.2012	Marked
42.	1402/6801	SHANTHI	35/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation,Acanthosis nigricans present	01.09.2012 to 13.10.2012	Marked
43.	168/4474	NEELAMANI	25/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	04.10.2012 to 24.10.2012	Marked
44.	1035/5859	SELVARANI	20/F	Irregular menstruation ,Oligomenorrhoea, Dysmenorrhoea, Constipation present	18.07.2012 to 28.08.2012	Marked

Sl. No.	O.P. No.	Name	Age/ Sex	BT & AT	HAEMATOLOGICAL PARAMETERS									URINE ANALYSIS		
					TC CU/mm	DC			ESR		Hb(gm)	B.S Mg/dl	S.Cho Mg/dl	ALB	SUG	DEP
						P	L	E	½ hr	1 hr						
1.	7349	DIANA	27/F	BT	9000	58	37	5	5	10	10.0	85	214	-	-	FPC
				AT	8100	56	39	6	6	12	12.5	90	172	-	-	-
2.	3517	KALAIMAGAL	20/F	BT	7600	52	42	6	8	16	9.0	95	178	-		-
				AT	5700	62	34	4	7	14	11.5	89	166	-	-	-
3.	3182	VALARMATHI	16/F	BT	6400	66	32	2	6	14	11.0	113	200	-		-
				AT	4900	54	40	6	5	12	11.5	98	179	-	-	FEC
4.	7464	UMAMAHESWARI	37/F	BT	6700	60	35	5	8	16	9.5	140	194	-	-	-
				AT	7800	63	35	2	7	14	11.0	98	167	-	-	-
5.	4189	RAJESWARI	27/F	BT	5900	59	37	4	10	20	12.0	104	168	-	-	FPC
				AT	6700	58	36	6	5	10	12.5	84	172	-	-	-
6.	2396	NITHYA	19/F	BT	5700	66	31	3	6	12	10.0	92	173	-	-	-
				AT	6800	65	34	1	7	14	11.0	102	156	-	-	FPC
7.	4283	DEEPAPRIYA	17/F	BT	9800	63	32	5	6	12	12.5	86	165	-	-	-
				AT	8500	64	30	6	7	14	12.5	96	169	-	-	-
8.	5245	SUGANYA	26/F	BT	6400	60	36	4	5	10	11.0	130	156	-	-	-
				AT	7800	62	33	5	8	16	12.0	104	164	-	-	-
9.	6482	NIRMALA	27/F	BT	9500	63	31	6	5	10	9.8	102	167	-	-	FEC
				AT	8100	65	35	0	7	14	12.2	98	178	-	-	-
10.	7146	PARVATHY	26/F	BT	5500	59	40	1	6	12	12.0	84	157	-	-	-
				AT	6100	65	34	1	7	14	12.0	95	162	-	-	-

Sl.No.	O.P. No.	Name	Age/ Sex	BT & AT	HAEMATOLOGICAL PARAMETERS									URINE ANALYSIS		
					TC CU/mm	DC			ESR		Hb(gm)	B.S Mg/dl	S.Cho Mg/dl	ALB	SUG	DEP
						P	L	E	½ hr	1 hr						
11.	7908	DHANALAKSHMI	30/F	BT	980790	56	38	6	4	8	11.0	89	168	-	-	-
				AT	8400	60	36	4	6	12	12.0	85	157	-	-	-
12.	8767	KALADEVI	32/F	BT	7600	64	31	5	7	14	9.8	96	179	-	-	-
				AT	8100	57	40	3	5	10	11.2	81	167	-	-	-
13.	8827	PRIYANKA	20/F	BT	5600	58	38	4	6	10	10.5	90	187	-	-	FEC
				AT	4900	60	35	5	5	12	12.4	98	165	-	-	-
14.	9110	KRISHNAKUMARI	/27F	BT	7500	61	37	2	4	10	12.0	85	155	-	-	-
				AT	6500	64	35	1	8	16	12.2	84	167	-	-	-
15.	168	SRIVALLI	38/F	BT	8700	60	33	7	5	16	8.8	105	178	-	-	FPC
				AT	5600	55	40	5	4	8	11.5	86	165	-	-	-
16.	1221	KARPAGAM	30/F	BT	6300	60	39	1	5	10	11.0	112	230	-	-	-
				AT	7200	62	38	0	6	12	12.0	90	185	-	-	-
17.	1371	ANITHA	29/F	BT	6700	58	37	5	5	10	10.0	98	156	-	-	-
				AT	5800	56	37	7	7	14	12.0	87	176	-	-	-
18.	5201	DIVYA	20/F	BT	6900	64	36	0	5	10	10.4	79	178	-	-	FPC
				AT	8700	55	38	7	4	12	12.4	84	168	-	-	-
19.	8395	SARALA	33/F	BT	9200	51	45	4	6	14	11.4	80	198	-	-	FEC
				AT	6400	57	38	5	6	12	12.6	87	157	-	-	-
20.	8825	CAROLIN MERY	30/F	BT	7900	65	34	1	5	10	11.0	130	187	-	-	-
				AT	6700	59	40	1	8	16	12.8	98	164	-	-	-

S. No.	O.P. No.	Name	Age/ Sex	BT & AT	HAEMATOLOGICAL PARAMETERS									URINE ANALYSIS		
					TC CU/mm	DC			ESR		Hb(gm)	B.S Mg/dl	S.Cho Mg/dl	ALB	SUG	DEP
						P	L	E	½ hr	1 hr						
21.	7710	VASANTHI	28/F	BT	8700	57	38	5	4	12	12.0	98	165	-	-	FEC
				AT	5400	63	37	0	6	16	12.4	95	154	-	-	-
22.	6619	FATHIMA	24/F	BT	4500	59	37	4	8	12	9.8	102	178	-	-	-
				AT	6800	65	35	0	5	14	12.2	86	167	-	-	-
23.	7779	AMUL	30/F	BT	9700	55	39	6	6	18	9.0	89	187	-	-	-
				AT	7600	66	30	4	8	15	11.5	92	165	-	-	FEC
24.	8005	LATHA	22/F	BT	5600	59	35	6	7	12	12.0	110	156	-	-	-
				AT	9100	60	37	3	4	18	12.6	94	178	-	-	-
25.	9657	DHANALAKSHMI	25/F	BT	5700	56	37	7	5	10	9.8	85	168	-	-	-
				AT	6700	60	34	6	6	12	11.8	79	155	-	-	-
26.	341	RADHA	26/F	BT	5700	65	30	5	8	14	11.4	88	178	-	-	-
				AT	5600	59	40	1	9	16	12.6	94	156	-	-	-
27.	1001	ARUNA	27/F	BT	5800	50	42	8	4	16	11.0	84	187	-	-	-
				AT	6800	67	40	3	5	14	12.4	81	164	-	-	-
28.	1672	MEENALOKSINI	26/F	BT	6900	61	37	2	7	12	10.8	92	173	-	-	FPC
				AT	7800	62	34	4	6	15	11.5	80	162	-	-	-
29.	1523	AMBIKA	17/F	BT	7200	54	40	6	7	12	11.0	118	184	-	-	-
				AT	5600	66	34	0	4	8	12.8	95	161	-	-	-
30.	1558	PIRAMILA	30/F	BT	6900	61	33	6	8	16	10.8	130	164	-	-	-
				AT	6100	59	40	1	6	12	12.6	96	153	-	-	FEC

S. No.	O.P. No.	Name	Age/ Sex	BT & AT	HAEMATOLOGICAL PARAMETERS									URINE ANALYSIS		
					TC CU/mm	DC			ESR		Hb(gm)	B.S Mg/dl	S.Cho Mg/dl	ALB	SUG	DEP
						P	L	E	½ hr	1 hr						
31.	1528	SUGANYA	17/F	BT	5400	62	34	4	5	10	11.5	86	165	-	-	FEC
				AT	6300	57	37	6	6	15	12.0	78	155	-	-	-
32.	1755	POWLIN SHANTHA	23/F	BT	7600	58	40	2	7	12	9.5	94	176	-	-	-
				AT	5200	59	36	5	8	16	11.5	84	165	-	-	-
33.	1761	RAJESWARI	31/F	BT	9100	56	32	6	5	10	9.8	76	187	-	-	-
				AT	6800	54	42	4	6	12	12.0	92	154	-	-	-
34.	2082	SUBHASINI	35/F	BT	7200	65	35	0	4	8	10.5	81	163	-	-	FPC
				AT	4500	61	38	1	9	18	12.2	86	172	-	-	-
35.	2288	SARASWATHY	23/F	BT	5700	55	38	7	6	14	9.5	140	185	-	-	-
				AT	6700	52	42	6	4	10	11.8	98	163	-	-	-
36.	2562	RADHIGA	25/F	BT	4500	59	41	0	8	16	10.5	87	178	-	-	FEC
				AT	6200	53	41	6	9	18	11.6	96	169	-	-	-
37.	2286	SOWMIYA	28/F	BT	8200	63	37	0	5	10	11.0	84	167	-	-	-
				AT	8300	67	30	3	7	14	12.0	82	157	-	-	FPC
38.	2564	AISHWARYA	21/F	BT	9800	65	32	3	8	15	12.5	94	156	-	-	-
				AT	4500	56	41	5	5	12	12.6	96	172	-	-	-
39.	2566	KAVYA	20/F	BT	6800	58	36	6	5	10	11.6	82	170	-	-	FEC
				AT	7100	57	40	3	8	18	12.2	79	165	-	-	-
40.	2557	DEEPA	31/F	BT	9600	67	29	4	6	14	8.8	85	154	-	-	-
				AT	5700	57	37	6	9	20	11.0	84	150	-	-	-

S. No.	O.P. No.	Name	Age/ Sex	BT & AT	HAEMATOLOGICAL PARAMETERS									URINE ANALYSIS		
					TC CU/mm	DC			ESR		Hb(gm)	B.S Mg/dl	S.Cho Mg/dl	ALB	SUG	DEP
						P	L	E	½ hr	1 hr						
41.	664/6045	SUGANYA	19/F	BT	5400	62	34	4	5	10	11.5	86	165	-	-	FEC
				AT	6300	57	37	6	6	15	12.0	78	155	-	-	-
42.	1402/6801	SHANTHI	35/F	BT	7600	58	40	2	7	12	9.5	94	176	-	-	-
				AT	5200	59	36	5	8	16	11.5	84	165	-	-	-
43.	168/4474	NEELAMANI	25/F	BT	9100	56	32	6	5	10	9.8	76	187	-	-	-
				AT	6800	54	42	4	6	12	12.0	92	154	-	-	-
44.	1035/5859	SELVARANI	20/F	BT	7200	65	35	0	4	8	10.5	81	163	-	-	FPC
				AT	4500	61	38	1	9	18	12.2	86	172	-	-	-

5. RESULTS AND DISCUSSION

The well known *Siddha* herbo – mineral drug *Navachara Chunnam* had been subjected to various studies to establish the works of *Siddhars* to be true. Literary collections, physicochemical and Elemental analysis, toxicological study, pharmacological study and clinical study are done to prove the activity of *Navachara Chunnam in PCOS (Polycystic ovarian syndrome)*

Navacharam, the chief ingredient of the medicine *Navachara chunnam*, is indicated for *soodhagakattu* in Siddha literature. In addition *Navacharam* is used as key ingredient in medical formulations like *Panchalavana dhravagam, Saara mezhugu, Kalingadhi mezhugu, Bojana sanjeevi legyam,* which are indicated for *soodhagakatti* and *soodhagavali*. The adjuvant for *Navachara chunnam* is stated as *sombu kudineer*. *Sombu kudineer* as a separate medicine have the property of curing soodhagavayu. Hence navachara chunnam indication for soothagakattu is justified based on the composition and adjuvant.

PHYSICO CHEMICAL ANALYSIS OF *NAVACHARA CHUNNAM*

Parameter	Mean Value
Loss on Drying at 105°C	NIL
Total Ash	82.036 %
Acid insoluble Ash	0.577 %
Particle size	Completely passes through sieve no.44
ph	13.5

Interpretation

The stability of a drug and its shelf –life is dependent on moisture content. Determination of moisture (Loss on drying) in a drug is one of the important test in pharmaceutical analysis. (Dr.A.V. Kasture 2008)

Physico chemical analysis of *Navachara chunnam* showed that Loss on drying (LOD) is nil which indicated that no moisture content present in the prepared medicine.

Increased Moisture content is the factor for instability of a drug and lesser shelf life of a drug. Since *Navachara Chunnam* was well prepared, it could get maximum stability and better shelf life. Longer shelf life for *Chunnam* said in *Siddha* literature is justified from the above observation.

Preliminary Chemical Analysis of *Navachara chunnam*

S.NO	TEST FOR CHEMICALS	RESULT
1.	Reducing sugar	Absent
2.	Starch	Absent
3.	Protein	Absent
4.	Amino acid	Absent
5.	Albumin	Absent
6.	Phosphate	Absent
7.	Sulphate	Present
8.	Chloride	Present
9.	Iron	Present
10.	Calcium	Present
11.	Sodium	Absent
12.	Potassium	Absent
13.	Zinc	Present
14.	Magnesium	Present
15.	Alkaloids	Absent
16.	Tannic acid	Absent

From the result of preliminary chemical analysis shows that trial drug has Sulphate, chloride, Iron, Calcium, Zinc and Magnesium

Interpretation

CALCIUM

Maturation of the immature oocyte and the activation and fertilization of the mature egg are two separate events. Both may be synchronized by changes in intracellular calcium.

Evidence now suggests that abnormalities in calcium regulation may understandably explain the clinical presentation of PCOS, Including the reproductive abnormalities and insulin resistance. This evidence is supported by several facts.

- The significance of calcium in egg activation and in triggering meiotic resumption
- The role of calcium in LH-induced meiotic maturation
- The function of calcium and vitamin D in insulin resistance
- The clinical evidence of abnormalities in calcium homeostasis in reproductive disturbance and in women with PCOS

Antagonizing the inhibitor with changes in calcium concentration can affect continuation of meiosis. Extra cellular stimulation of the oocyte with calcium, gonadotropins and various growth factors results in changes in intracellular calcium concentrations via transmembrane movements between cytosol and internal organelles, representing are important signalling mechanism.

Calcium homeostasis in the setting of various hormones and growth factors determines the ultimate biochemical pathway selected in the phosphoinositide or adenylate cyclase-dependent protein kinase C system of reproduction and oocyte maturation.

More recently, calcium has identified as an important mineral nutrient in fertility. Vitamin D receptor knockout mice have low serum calcium concentration and are infertile. (Connie M.Weaver *et al* 2006)

Zinc and Reproduction

Zn is essential for proper reproduction (Biochemistry-Sathyanarayana)

Magnesium and insulin resistance

Magnesium is necessary for the action of insulin and the manufacture of insulin. Recent studies shows that an association between insulin resistance and magnesium deficiency. Mg deficiency is relatively common in diabetic individual (Nancy Dunne *et al*). Insulin resistance is one of the most important clinical features of PCOS.

ELEMENTAL ANALTSIS OF DRUG

Fourier Transforms Infrared Spectroscopy (FT-IR):

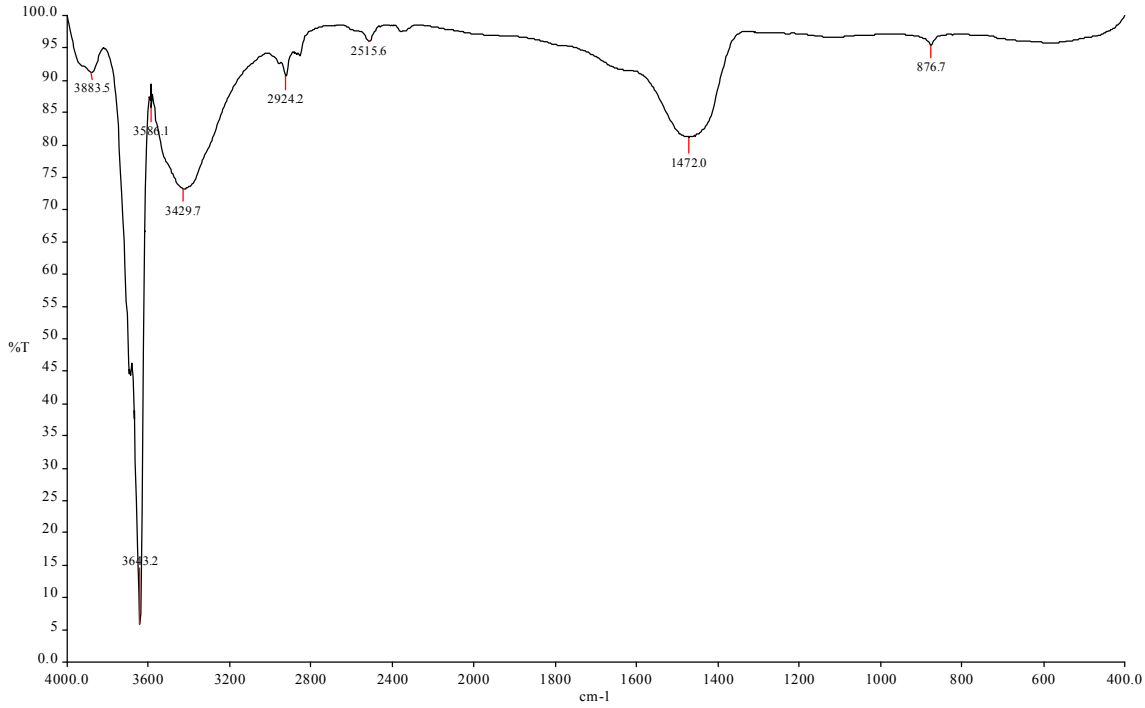


Fig no-4 FT-IR analysis

FTIR is the acronym for Fourier Transform Infrared Spectroscopy. FTIR is a spectroscopic technique that utilizes lower energy radiation to induce vibration and rational excitation of atoms and groups of atoms within molecules. Because of the variety of symmetry of atomic groups and their differences in atomic masses and electronic structure the absorption patterns for a specific species will be unique, which allows for their identification. Infrared spectroscopic technique used to recognize the functional groups in organic and inorganic compounds.

Principle

IR interacts with the sample and the bonds between atoms in the molecule stretch and bend, absorbing infrared energy and creating the infrared spectrum. It is of two types bending and stretching.

FT-IR is a very useful tool in the detection of the functional groups of bio molecules, thus aiding in their structural elucidation, thereby confirming the presence of active molecules responsible for the therapeutic activity of *Siddha* drugs.

Navachara chunnam have following function groups.

PEAK VALUES	FUNCTIONAL GROUPS
3883.5	Phenols and alcohols
3643.2	Phenols and alcohols
3586.1	Phenols and alcohols
3429.7	Phenols and alcohols
2924.2	Alkanes
2515.6	Carboxylic acids
1472.0	Alkanes
876.5	Aromatic group

Interpretation

Phenolic groups act as an anti-oxidant (Modern uses for ancient medicine 2009). Increased oxidative stress and decreased antioxidant capability in women with PCOS could be a causative factor to the increased risk of cardiovascular disease in adding to typical risk factors as insulin resistance, hypertension, obesity and dyslipidemia.(Gabor Kovacs *et al* 2007).*Navachara chunnam* which has phenolic groups may be act as an anti-oxidant and to prevent classical risk factors of PCOS like cardiovascular disease, insulin resistance, obesity, dyslipidemia and hypertension.

SCANNING ELECTRON MICROSCOPE (SEM):

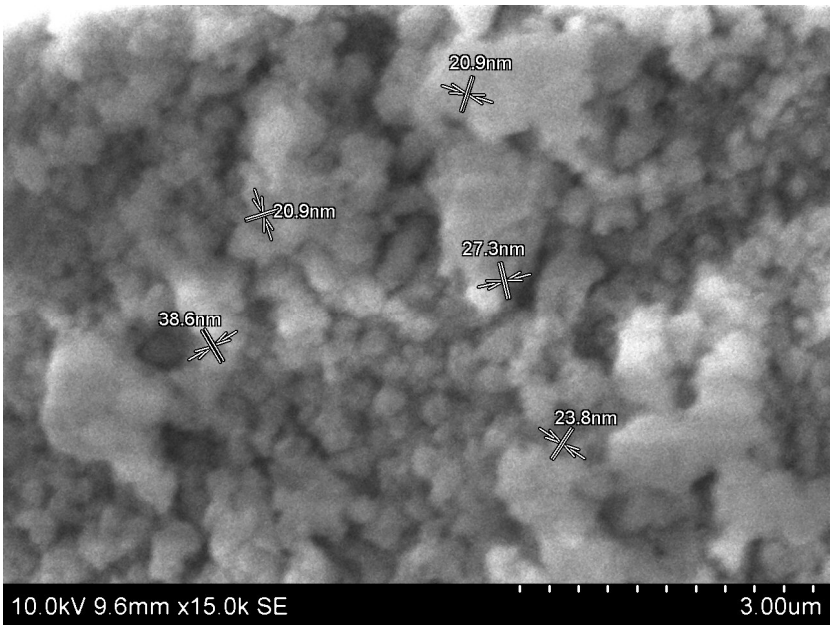


Fig No-5-SEM analysis

Electron Microscopes are scientific instruments that use a beam of highly energetic electrons to examine objects on a very fine scale. This examination can yield information about the topography (surface features of an object) morphology (shape and size of the particles making up the objects) composition (the elements and compounds that the object is composed of the relative amounts of them) and crystallographic information (how the atoms are arranged in the object)

Nanoparticles have valuable properties that can be used to improve drug delivery. Where larger particles would have been unfurnished from the body, cells take up these nanoparticles because of their size. Complex drug delivery mechanisms are being developed, together with the ability to get drugs through cell membranes and into cell cytoplasm. Effectiveness is important because many diseases depend upon processes within the cell and can only be impeded by drugs that make their way into the cell. (Bertrand N *et al*, 2011)

ACUTE AND SUBACUTE TOXICITY ON *NAVACHARA CHUNNAM*

The results of haematological investigations revealed significant changes in the different parameters investigated compared with those of respective control. All the animals from control group were survived throughout the dosing period of 28 days but the *Navachara Chunnam* higher dose treated group showed toxic symptoms like itching, writhing and muscle paralysis with loss of gripping response. Two animals were died after 15 days of treatment.

Animals from all the treated dose groups exhibited minimum body weight gain with that of controls throughout the dosing period of 28 days. Food consumption in treated animals was found to be reduced and water intake (Data not shown) was increased gradually at high dose group throughout the dosing period of 28days. Ophthalmoscopic examination, conducted prior to and at the end of dosing period on animals from control and all the treated dose groups did not reveal any abnormality. Functional observation tests conducted at termination revealed no abnormalities. Urine analysis, conducted at the end of the dosing period in week 4 revealed color and pH changes after treatment.

Organ weight data of animals sacrificed at the end of the dosing period was found to be comparable except kidney, testis and liver with that of respective control. Gross pathological examination did not reveal any abnormality. Histopathological examination reveal as follows. In stomach with superficial erosion and congestion, Liver: shows marked dilatation of sinusoids, degeneration of hepatocytes, necrosis. Kidney: shows renal tissue with tubular epithelial damage. Testis: Giant cells were formed in the lumen of the seminiferous tubules and the spermatogenic cells degenerated. Lung: shows congestion, narrowed alveolar space and thickened alveolar wall. Ovary: shows increased ovarian follicles and corpus leuteum. Remaining organ architecture was found to be normal.

These finding indicates that the *Navachara chunnam* has toxic effect upto 50mg/kg onwards treated via oral route over a period of 28 days. So, it can be concluded that the *Navachara Chunnam* can be prescribed for therapeutic use in human with the dosage of upto maximum of 25mg/kg. body weight p.o. But for the long term use the dose reduction is recommended to prevent hepatic and renal complications.

Table 3: Dose finding experiment and its behavioral Signs of Toxicity

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	**500**	+	-	-	+	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-
2	**1000**	+	+	-	+	-	+	+	+	-	+	-	-	-	-	-	-	-	+	+	+
3	**2000**	+	+	-	+	-	+	+	+	+	+	+	-	-	-	-	-	-	+	+	+

1. Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhoea 18. Writhing 19. Respiration 20. Mortality

Table 4: Organ weights of rats in the sub acute toxicity study of the Navachara chunnam.

Parameter	Control	Navachara chunnam		
		25mg/kg	**50mg/kg**	**100mg/kg**
Brain	2.04±0.03	1.95±0.03	1.99±0.03	2.00±0.04
Lungs	2.24±0.04	2.18±0.05	2.09±0.06	1.90±0.08*
Heart	1.83±0.06	1.68±0.05	1.71±0.07	1.79±0.09
Liver	18.50±0.53	14.68±0.44*	15.17±0.58*	13.50±0.56**
Pancreas	1.99±0.18	1.77±0.13	1.70±0.12	1.74±0.14
Spleen	1.10±0.07	1.04±0.02	1.04±0.04	1.06±0.03
Ovary	1.03±0.04	1.15±0.02*	1.22±0.05**	1.26±0.02**
Kidneys	1.90±0.05	1.80±0.03	1.61±0.04	1.37±0.07
Testis	1.98±0.05	1.96±0.06	1.99±0.04	2.09±0.04

Values are expressed as mean + S.E.M., n = 6; *p<0.05; **p<0.01 significantly different from control.

Table 5: Effect of Navachara chunnam on Body weight of rats.

Treatment	Day 1	Day 4	Day 8	Day 12	Day 16*	Day 20**	Day 24**	Day 28**
Control	158.02± 2.4	162.00± 2.12	164.11± 1.74	166.51± 1.12	167.12± 2.20	168.54±2 .11	168.05± 2.32	170.14± 2.51
25mg/kg	151.00± 1.2	152.12± 1.4	151.3±1 .2	151.6±1 .82	148.51± 1.20	147.50±1 .2	145.3±1 .3	146.5±2 .2
50mg/kg	150.02± 1.12	152.20± 1.10	151.7±1 .79	150.04± 1.4	152.41± 1.30	140.25±2 .36	140.20± 2.3	135.06± 2.01
100mg/kg	150.12± 1.34	150.27± 1.42	148.26± 3.25	148.22± 2.02	143.11±2. 7	142.55 ±1.6	140.14± 1.10	140.52± 0.32

Values are expressed as mean + S.E.M., n = 6; *p<0.05; **p<0.01 significantly different from control.

Table 6: Effect of Navachara chunnam on Heamatological and Biochemical profile of rats

Parameter	Treatment and Dose			
	Control	**Navachara Chunnam (25mg/kg)**	**Navachara Chunnam (50mg/kg)**	**Navachara Chunnam (100mg/kg)**
WBC($X10^3$/µL)	11.4±3.1	10.72±2.4	10.10±2.2	10.16±2.5
RBC($X10^{12}$/l)	7.14±0.38	7.92±0.46	8.12±0.52	7.00±0.50
Hemoglobin(g/dl)	13.44±0.32	15.10±0.35*	14.52±0.40	15.11±0.44*
MCV (fl)	53±0.47	53.52±3.20	52.55±6.42	60.17±8.07*
MCHC (g/dl)	35.14±1.5	27.11±1.80**	37.20±1.58	30.10±1.40*
MCH (pg)	20±0.2	23±0.1*	24±0.3**	25±0.3**
Platelet count ($X10^9$/l)	882.75±20.2	785.44±17.38*	784.40±28.12*	885.18±25.51
Bilirubin	1.33±0.04	1.28±0.02	1.34±0.05	1.31±0.02
ALT (µ/l)	35.38±2.2	24.50±1.40**	26.12±2.10**	27.00±1.43**
AST (µ/l)	184.90±5.4	125.16±6.22**	130.69±6.20**	147.11±7.00**
Creatinine (µ/l)	0.32±0.04	0.46±0.05**	0.40±0.06**	0.47±0.04**
Cholesterol (mmol/l)	33.83±3.3	34.8±3.2	40.02±2.5	44.2±2.9**
ALP	54.58±3.2	68.80±2.84**	63.60±3.28	66.60±4.29*
Triglyceride	27.80±5.4	25.16±4.7	25.26±4.3	24.15±3.5
BUN (mg/dL)	25.60±0.98	24.02±1.10	24.60±1.42	25.14±1.82
Glucose (mg/dL)	99.30±3.72	99.10±5.37	99.70±8.22	98.57±7.33

Values are expressed as mean + S.E.M., n = 6; *p<0.05; **p<0.01 significantly different from control.

Table 7: Urine Analysis

Parameters	**Control**	**25 mg/kg**	**50 mg/kg**	**100 mg/kg**
Colour	Yellow	Yellow	Yellow	Yellow
Transparency	Clear	Slightly turbid	Cloudy	Turbid
Specific gravity	1.010	1.010	1.010	1.010
PH	>7.2	>8.0	>8.0	>9.0
Protein	Nil	1+	3+	2+
Glucose	Nil	Nil	Nil	Nil
Bilirubin	-ve	-ve	-ve	-ve
Ketones	-ve	+ve	+ve	+ve
Blood	Absent	Absent	Absent	Absent
UROBILINOGEN	Normal	Abnormal	Abnormal	Abnormal
Pus cells	0-cells/HPF	1-cell/HPF	2-cells/HPF	1-cell/HPF
RBCs	Nil	Nil	0-1cells/HPF	Nil
Epithelial cells	Nil	1-cell/HPF	Nil	1-cell/HPF
Crystals	Nil	Nil	Nil	Nil
Casts	Nil	Nil	Nil	Nil
Others	Bacteria seen	Bacteria seen	Bacteria seen	Bacteria seen

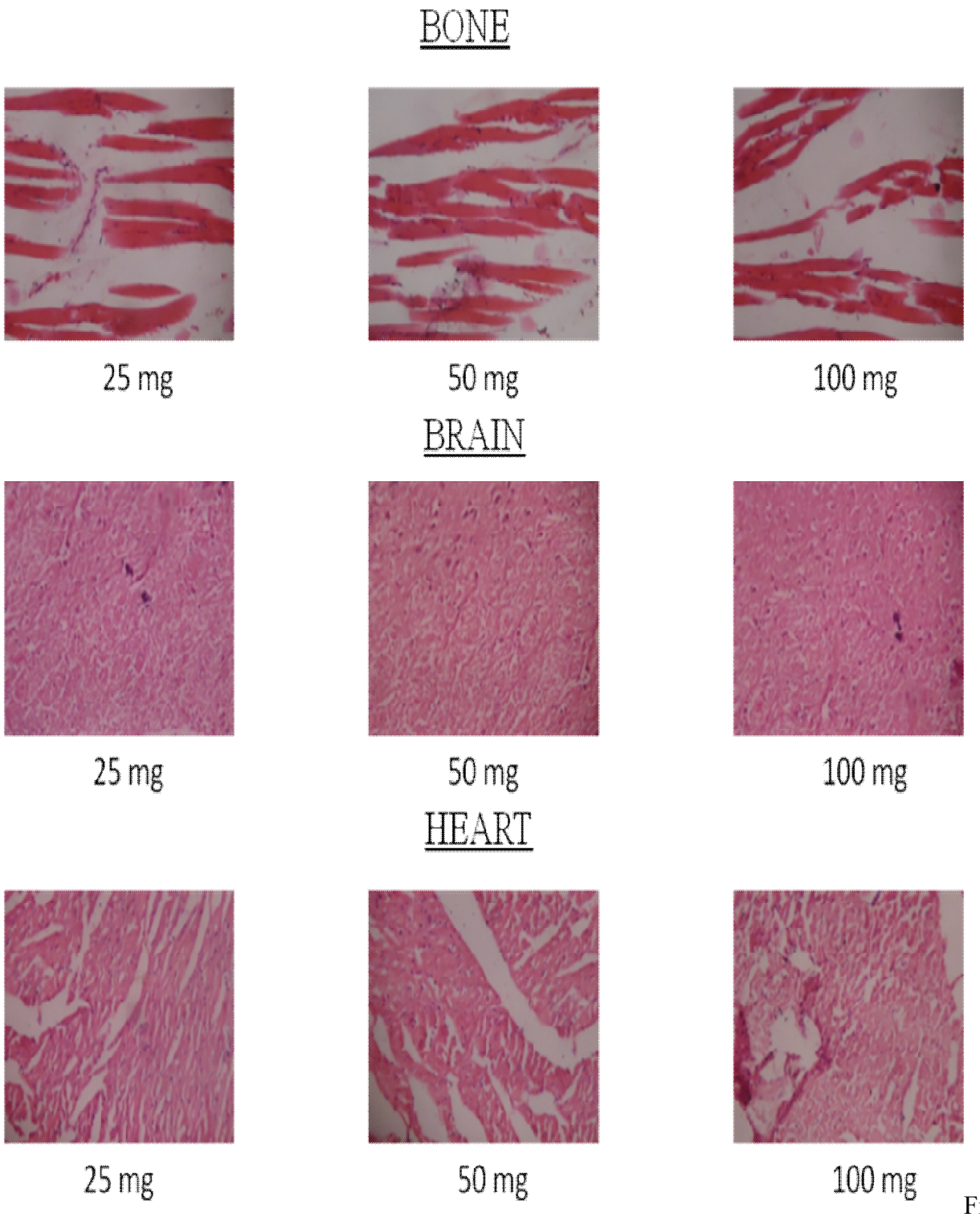


Fig No.6-Subacute toxicity of Navachara chunnam (Histopathology)

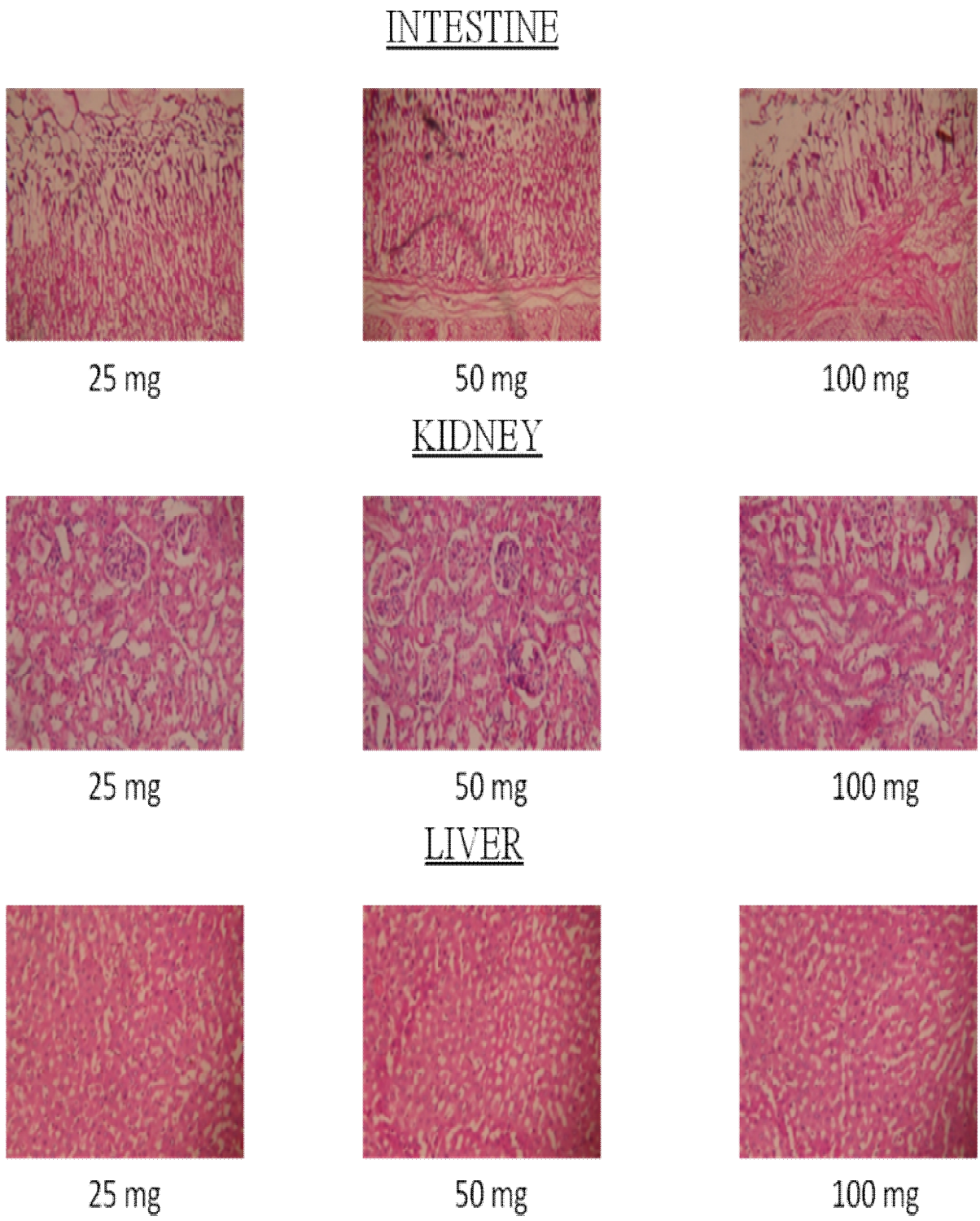


Fig.No.7- Subacute toxicity of Navachara chunnam (Histopathology)

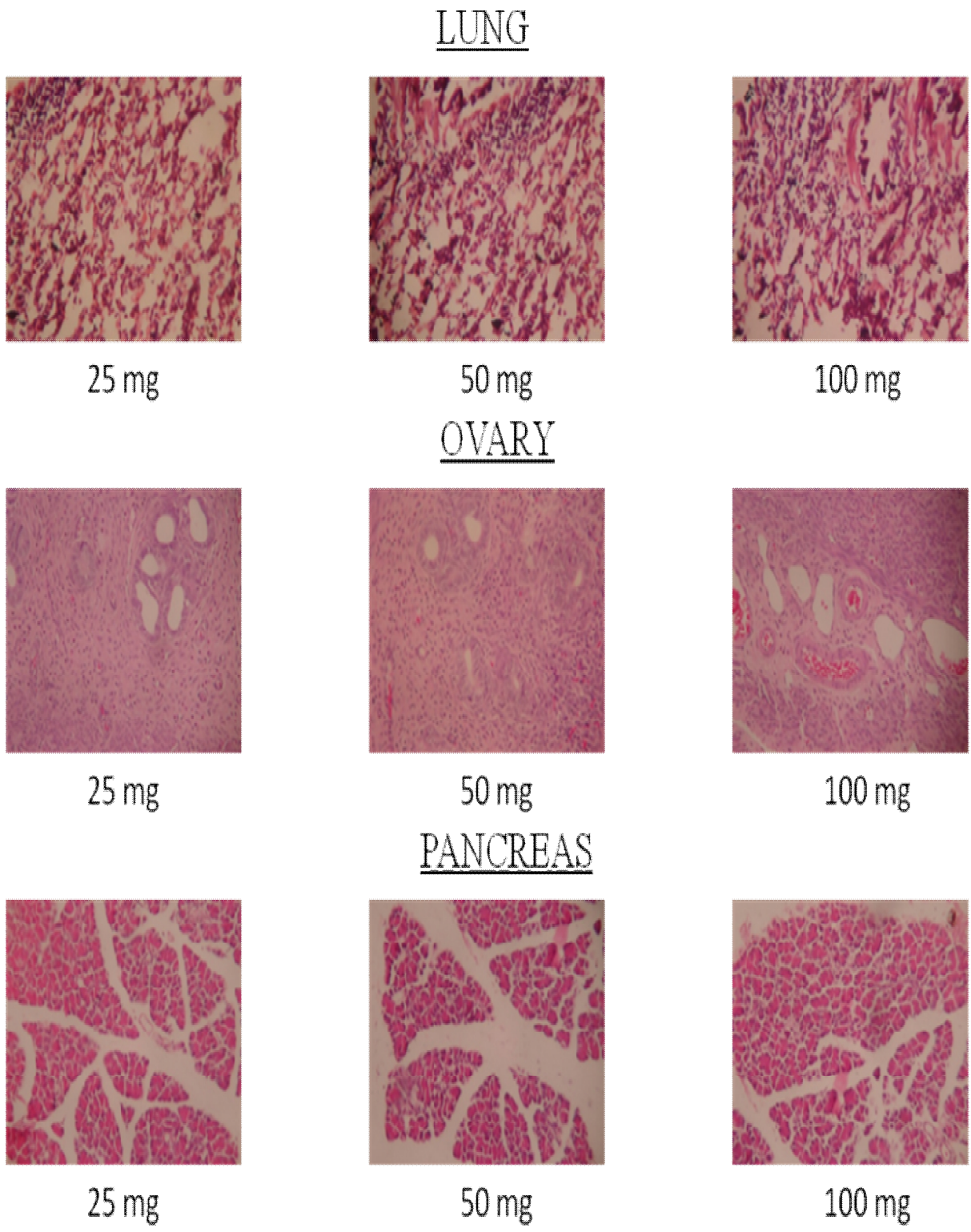


Fig.No.8- Subacute toxicity of Navachara chunnam (Histopathology)

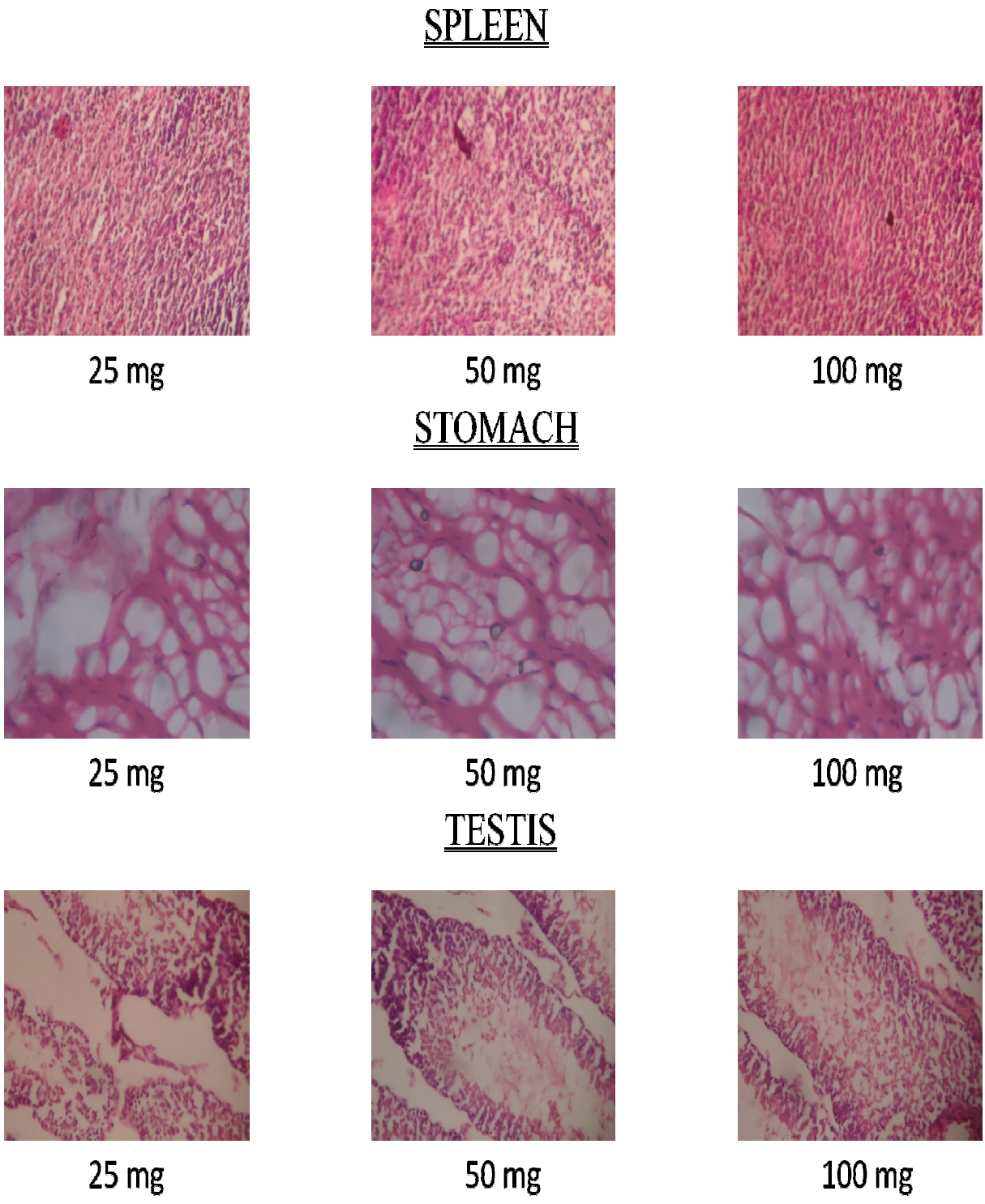


Fig.No.9 Subacute toxicity of Navachara chunnam (Histopathology)

EVALUATION OF OVULOGENIC EFFECT OF NAVACHARA CHUNNAM IN RATS

RESULTS AND DISCUSSION

Polycystic ovary syndrome is an endocrine disorder that affects approximately 5% of all women. It occurs amongst all races and nationalities, is the most common hormonal disorder among women of reproductive age, and is a leading cause of infertility. The principal features are obesity, anovulation and/or menstruation, and excessive amounts or effects of androgenic hormones. The symptoms and severity of the syndrome vary greatly among women. While the causes are unknown, insulin resistance, diabetes, and obesity are all strongly correlated with PCOS. Based on symptomatology incidence varies between 4-5% to 21% (menstrual abnormalities) and 3.5 to 9% (hyperandrogenism). It is important to remember that, 40% of women with oligomenorrhoea, 84% of women with hirsutism and 100% of women presenting with severe acne, have PCOS as their etiology.

Due to the side effects of many chemical drugs, the alternative use of traditional medications has greatly increased within the past decade. Successful growth and differentiation of the ovarian follicle is known to be under the control of the follicle-stimulating hormone (FSH) and luteinizing hormone (LH) produced by the pituitary. Many recent *in vitro* and *in vivo* studies have shown that the process of folliculogenesis is mediated by cAMP and is modulated by many local paracrine and autocrine factors in addition to the gonadotrophins themselves. These modulatory factors include steroid hormones and non-steroidal factors such as growth factors.

Although gonadotrophins are required for folliculogenesis, factors that regulate the cyclic appearance and atresia of dominant follicles and other follicles of variable size are of great significance. Various factors causing and regulating follicular atresia may include age, stage of the reproductive cycle, pregnancy, lactation, hormones of extraovarian or intraovarian sources.

Follicular growth is regulated by endocrine (FSH, LH and prolactin) and local (paracrine and autocrine) factors. The latter include steroid hormones (e.g., progestins, estrogens and androgens) produced by different cell types of the ovary and various non-steroidal regulators (e.g., oocyte maturation inhibitor, luteinization stimulator, luteinization inhibitor, FSH inhibitor, insulin-like growth factors, transforming growth factors, epidermal growth factor, platelet-derived growth factor, inhibin, and activin). Many of the changes occurring during oocyte growth and maturation also appear to be

mediated or influenced by ions, hormones (especially gonadotrophins and steroids) and endogenous cytoplasmic factors such as maturation promoting factor and growth factors.

Treatment with doses of 25 and 50 mg/kg of *Navachara Chunnam* significantly increased the number of primordial follicles ($p<0.05$ for 25 mg/kg; $p<0.01$ for 50 mg/kg;). This increase was also observed in the number of primary follicles, however it was significant only in the 50mg/kg group ($p<0.01$,). Treatment with 25 and 50 mg/kg dosages decreased the number of preantral and antral follicles, however, this decrease was significant only in the 50 mg/kg group ($p<0.05$). Different dosages of the *Navachara Chunnam* slightly increased the number of atretic follicles; a greater increase was observed at 50 mg/kg ($p>0.05$).

The treatment with both doses of *Navachara Chunnam* caused an alterations in the amount FSH, which was statistically significant. *Navachara Chunnam* in the first stages of folliculogenesis strongly increased the number of primordial follicles. This increase was more pronounced at the 50mg/kg dose of the *Navachara Chunnam* acted as a stimulant, causing progression of folliculogenesis to the stage of primary follicle formation. However, at the next stage of folliculogenesis. *Navachara Chunnam* caused an increase in the number of growing follicles. The *Navachara Chunnam* also caused an increase in the number of atretic follicles, which confirmed the repressing effect of the *Navachara Chunnam* on the natural growth of follicles, which seems reasonable considering the slight decrease in the level of FSH.

The results of ovulation effect revealed the significant influence at the dose level of 25mg/kg and this marked effect was ensured with the histological evaluation of uterus of experimental rats also. Hence it may be concluded that the *Navachara Chunnam* is a excellent traditional medicine in the treatment for anovulatory conditions like PCOS and the effect may be attributed to the elevation of the ovulation stimulatory hormones in animal models.

Table-8: Effect of Navachara Chunnam on weight of uterus and ovary after 10 days treatment

S.No	Group	Treatment and dose	Weight of uterus (mg)	Weight of ovary (g)
1.	Normal	2ml/kg 2% CMC	16.10±1.24	1.65±0.12
2.	Test-I	Navachara Chunnam 25mg/kg	14.22±0.56	1.45±0.14
3.	Test-II	Navachara Chunnam 50mg/kg	15.31±1.00	1.51±0.10
4.	Standard	Clomiphene 10mg/kg	15.48±+0.68	1.72±0.15

N = 6. Values are expressed as Mean±SEM. $^{ns}P>0.05$ compared to normal control.

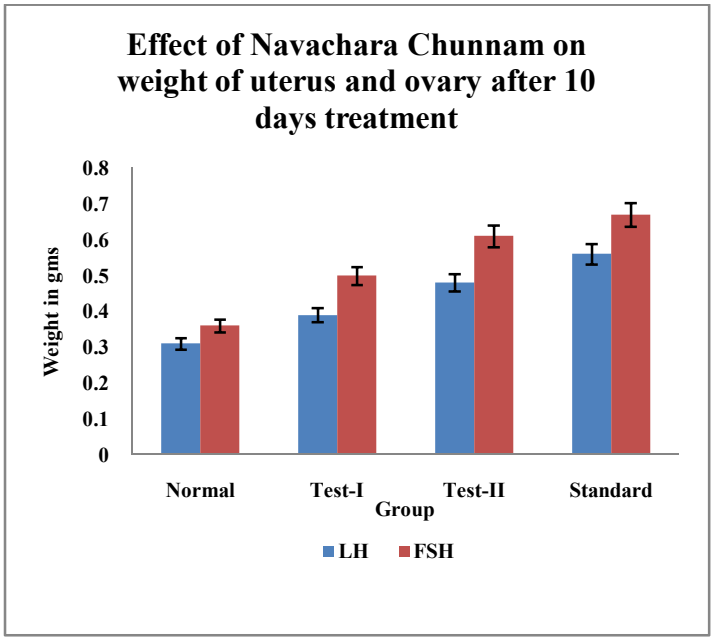
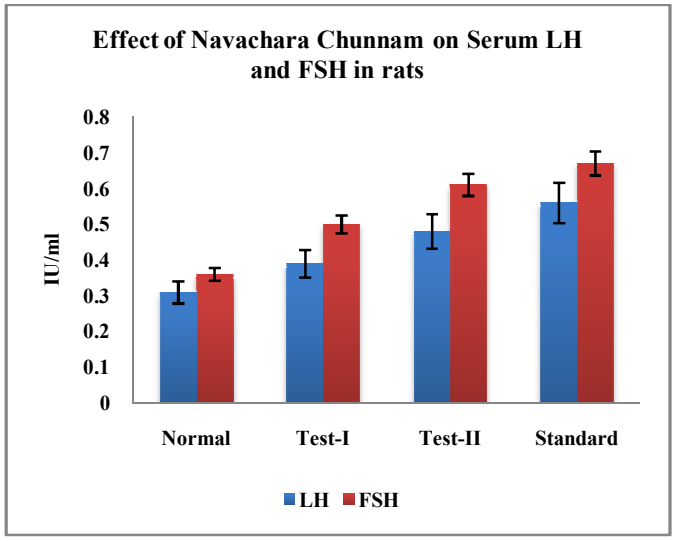
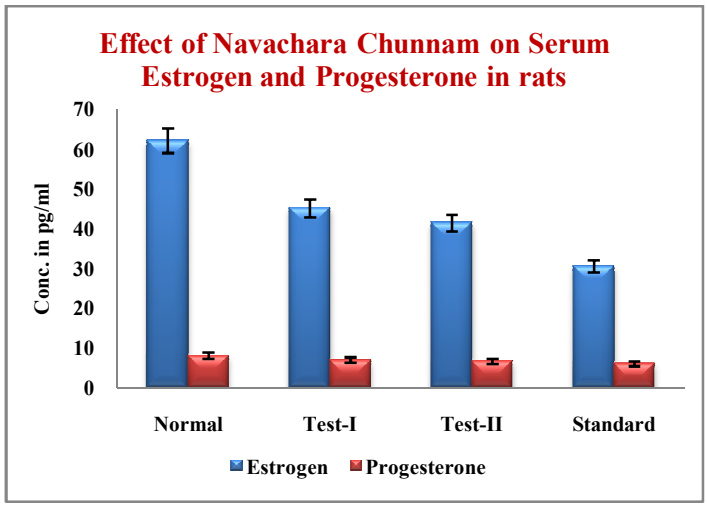


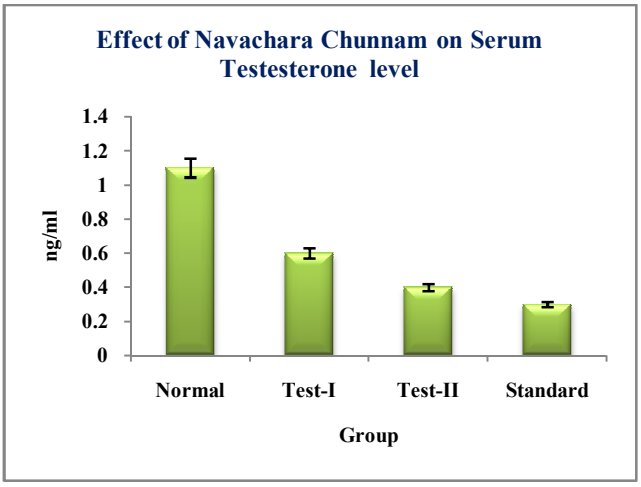
Table-9: Effect of *Navachara Chunnam* on Serum Concentration of reproductive hormones of female rats after 10 days treatment.

S.No	Group	Treatment and dose	LH (IU/ml)	FSH (IU/ml)	Estrogen (pg/ml)	Progesterone (pg/ml)	Testesterone (ng/ml)
1.	Normal	2ml/kg 2% CMC	0.31±0.06	0.36±0.04	62.24±3.2	8.2±1.12	1.1±0.10
2.	Test-I	Navachara Chunnam 25mg/kg	0.39±0.08	0.50±0.06	45.27±2.2^{*,a}	7.1±1.00	0.6±0.05^{**,a}
3.	Test-II	Navachara Chunnam 50mg/kg	0.48±0.08	0.61±0.08*	41.55±1.4^{*,a}	6.8±0.82	0.4±0.03**
4.	Standard	Clomiphene 10mg/kg	0.56±0.14	0.67±0.10*	30.62±1.0*	6.2±0.61	0.3±0.02**

N = 6. Values are expressed as Mean±SEM. *p<0.05;**p<0.01 Vs Normal control; ^{a}p<0.01 Vs Standard.


Effect of Navachara Chunnam on Serum LH and FSH in rats
IU/ml
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Normal
Test-I
Test-II
Standard
LH
FSH


Effect of Navachara Chunnam on Serum Estrogen and Progesterone in rats
Conc. in pg/ml
70
60
50
40
30
20
10
0
Normal
Test-I
Test-II
Standard
Estrogen
Progesterone


Effect of Navachara Chunnam on Serum Testesterone level
ng/ml
1.4
1.2
1
0.8
0.6
0.4
0.2
0
Normal
Test-I
Test-II
Standard
Group

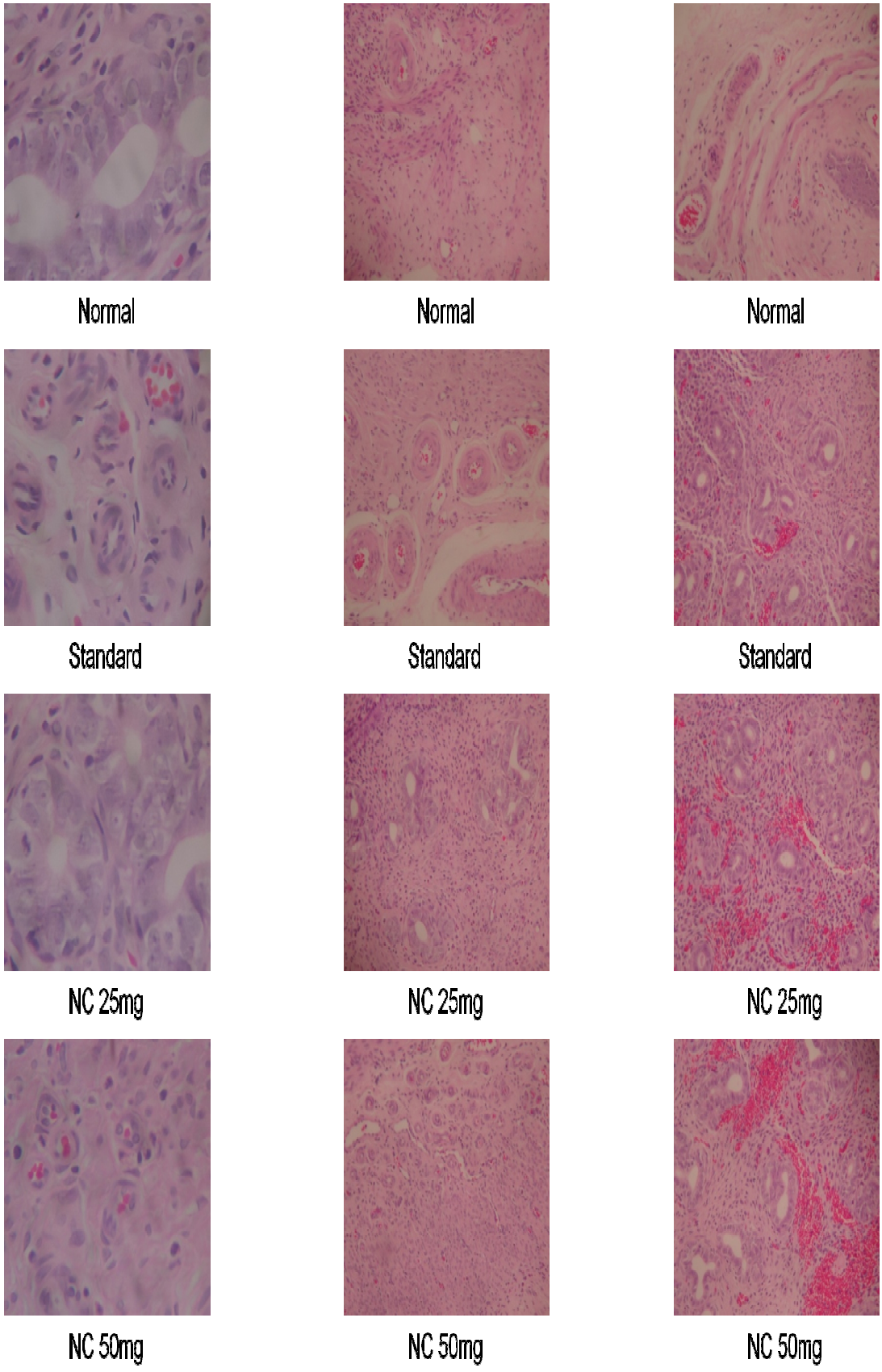


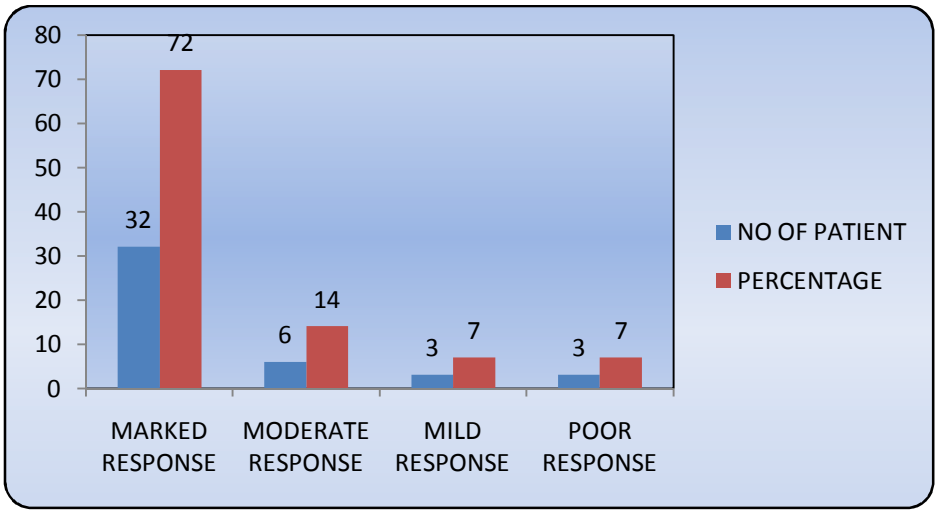
Fig.No.10. Ovulogenic activity of NC

4.5 CLINICAL ASSESMENT OF *NAVACHARA CHUNNAM:*

44 women with PCOS, age between 16-38 year were selected for open label clinical trial. Among 44 patients 40 patients were treated as out-patients, 4 patients were treated as in-patients. The selection was based on the inclusion and exclusion criteria. They were clinically diagnosed on the basis of *siddha* principles with modern laboratory findings.

Table No. 10-(Gradation result)

S. NO	LEVEL OF IMPROVEMENT	NO.OF PATIENTS	PERCENTAGE (%)
1.	Marked Response	32	72
2.	Moderate Response	6	14
3.	Mild Response	3	7
4.	Poor Response	3	7
TOTAL		44	100



Inference :

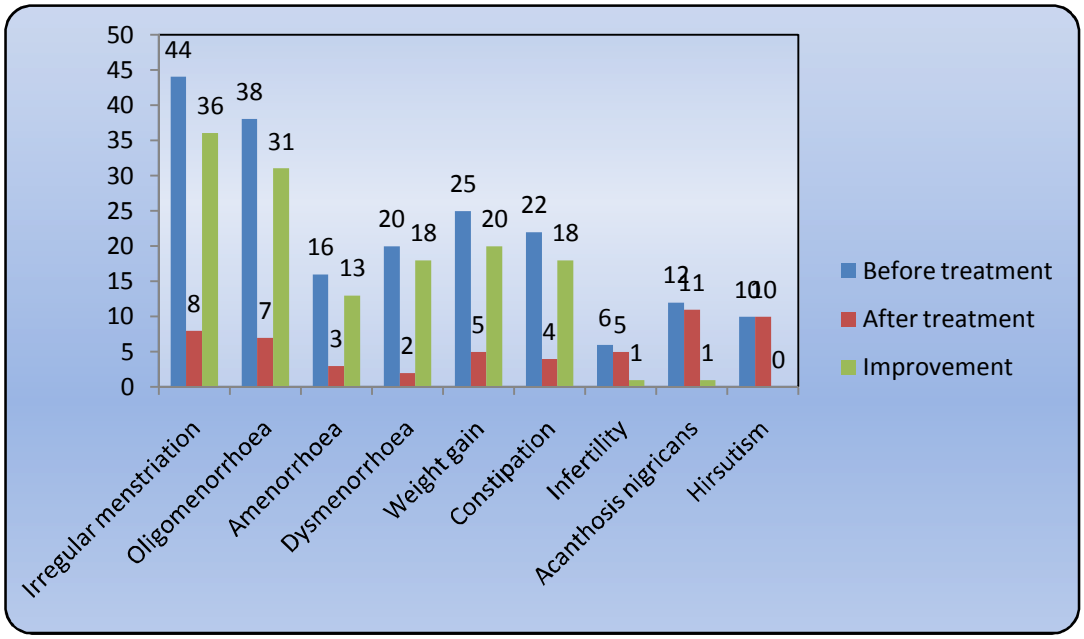
32 patients had marked response

6 patients had moderate response

3 patients had mild response

Table No. 11- (Improvement in signs and symptoms)

SL.NO	SIGNS AND SYMPTOMS	No of Patients			
		BT	AT	IMP	IMP %
1.	Irregular Menstruation	44	8	36	81
2.	Oligomenorrhoea	38	7	31	82
3.	Amenorrhoea	16	3	13	81
4.	Dysmenorrhoea	20	2	18	90
5.	Weight Gain	25	5	20	80
6.	Constipation	22	4	18	82
7.	Infertility	6	5	1	17
8.	Acanthosis nigricans	12	11	1	8.3
9.	Hirsutism	10	10	0	0



Inference

Among 44 patients,

- 36 out of 44 patients were relieved from Irregular Menstruation.
- 31 out of 38 patients were relieved from Oligo Menorrhoea.
- 13 out of 16 patients were relieved from Amenorrhoea.
- 18 out of 20 patients were relieved from Dysmenorrhoea.
- 20 out of 25 patients were reduced weight.
- 1 out of 6 patient was conceived.

USG-PELVIS

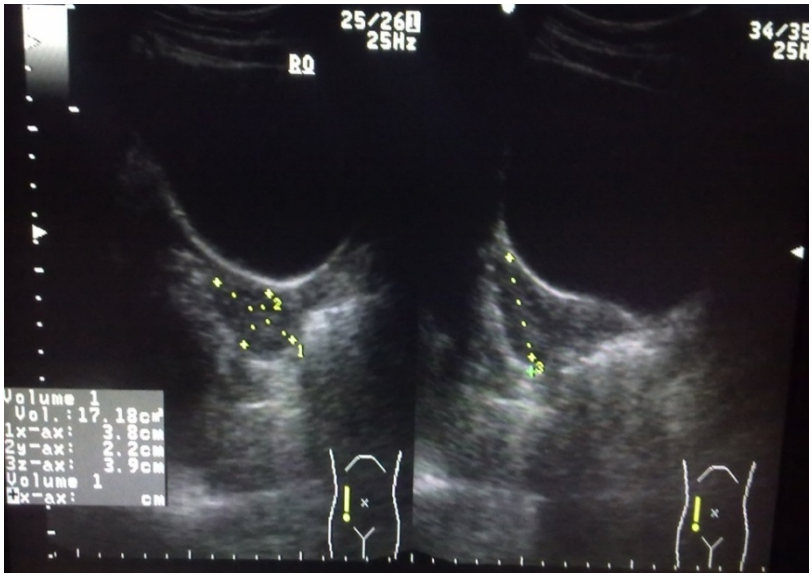


Fig No.11- Polycystic appearance of ovary (Before treatment)

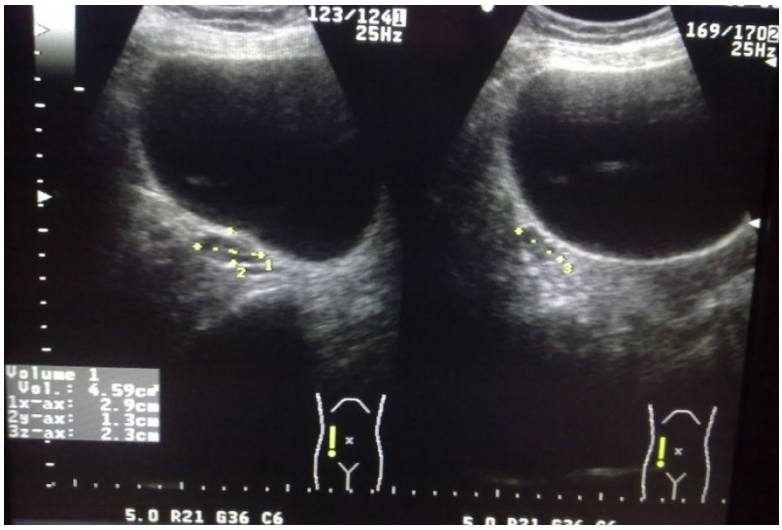


Fig No.12- After treatment

STATISTICAL ANALYSIS

DESCRIPTIVE STATISTICAL FOR IMPROVEMENT IN SIGN & SYMPTOMS IN PCOS (POLYCYSTIC OVARIAN SYNDROME) PATIENTS

PAIRED "t" TEST RESULT:
BMI (BODY MASS INDEX) IN PCOS PATIENTS

P value and statistical significance:

The two-tailed P value is less than 0.0001

By conventional criteria,this difference is considered to be extremely statistically significant.

Confidence interval:

The mean of Before treatment minus After treatment equals 3.295

95% confidence interval of this difference: From 3.011 to 3.580

Intermediate values used in calculations:

t = 23.3521

df = 43

standard error of difference = 0.141

Group	Before treatment	After treatment
Mean	27.686	24.391
SD	1.832	1.612
SEM	0.276	0.243
N	44	44

6. CONCLUSION

Navachara Chunnam is selected from the classical Siddha text *Anubhoga Vaidhya Navaneetham* for the evaluation of its therapeutic efficacy on Polycystic ovarian syndrome*(Sudhagakatti)*.

Physico chemically, *Navachara chunnam* with Nil Loss on drying(LOD) has Longer shelf life. *Navachara chunnam* contain Calcium which may act in PCOS to regulate oocyte maturation and the activation and fertilization of the mature egg. Navachara chunnam contains Zinc, which is essential for reproduction. Presence of Mg in Navachara chunnam may be useful in insulin action in PCOS.

SEM analysis revealed the size of the drug particle is in nanometer which implies that the drug could have potent drug delivery. FT-IR analysis disclosed the presence of Phenolic groups which could act as an anti-oxidant and prevent classical risk factors of PCOS like cardiovascular disease, insulin resistance, obesity, dyslipidemia and hypertension.

The results of ovulation effect in Rats revealed the significant influence at the dose level of 25mg/kg and this marked effect was ensured with the histological evaluation of uterus of experimental rats also. Hence it may be concluded that the *Navachara Chunnam* is an excellent traditional medicine in the treatment for anovulatory conditions like PCOS and the effect may be attributed to the elevation of the ovulation stimulatory hormones in animal models.

In Open clinical trial the drug has showed 72% marked response to PCOS. There were no new adverse drug reactions noticed during the course of the treatment.

As all the studies about *Navacharam chunnam* add beneficiary values for the therapeutic efficacy for PCOS it can be concluded that *Navachara chunnam* could be a scientifically validated and proven drug of choice for the management of PCOS*(Sudhagakatti)*.

7. SUMMARY

The trial drug *Navachara Chunnam* is selected from the classical Siddha text *Anubhoga Vaidhya Navaneetham* for the evaluation of its therapeutic efficacy on Polycystic ovarian syndrome*(Sudhagakatti)*. In the Introduction, the need to explore a new drug and the lacuna in present day management of PCOS is signified.

In Drug review, *Navacharam* is viewed in the field of General characters, therapeutic action and its presence in Siddha formulations indicated for female reproductive disorders. The uniqueness of *Chunnam* medicines expounded by siddhars are highlighted. Disease review explored the collection of Siddha literature as well as present scientific view about PCOS.

To standardize the drug, Physical and chemical study of the drug was done at SCRI, Arumbakkam, Chennai. Instrumental analysis for the drug was done at Anna University, Chennai. SEM analysis revealed the size of the drug particle is in Nanometer which implies that the drug could have potent drug delivery. FTIR analysis disclosed the presence of Phenolic groups which could act as an anti-oxidant and prevent classical risk factors of PCOS.

. The results of ovulation effect in Rats revealed the significant influence at the dose level of 25mg/kg and this marked effect was ensured with the histological evaluation of uterus of experimental rats also. Hence it may be concluded that the Navachara Chunnam is an excellent traditional medicine in the treatment for anovulatory conditions like PCOS and the effect may be attributed to the elevation of the ovulation stimulatory hormones in animal models.

In Clinical study, Open clinical trial was conducted in 44 patients at Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Chennai. The drug has shown significant improvement in Polycystic ovarian patients.

The final Discussion and conclusion chapters analyzed the dissertation. The conclusion chapter also provides a discussion of the verification and validity of the research results carried out. The most vital part of some experience of the findings in the dissertation is also discussed and thereafter invites the reader to further studies and future research possibilities.

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GOVT. SIDDHA MEDICAL COLLEGE & HOSPITAL

CHENNAI-106

M.D(S) - Branch II (GUNAPADAM)

Name of the medicine : ***Aivaeli samoola chooranam***

Name of the disease : ***Karappan* (Eczema)**

Dose & Adjuvant : 1 gm Bd after food with sugar

O.P. NO :	Date :	Height :
Name :	Age/Sex :	Weight :
Address :		BP :
Occupation :	Marital status :	PR :

SIGNS&SYMPTOMS	WEEKS								
	0	1	2	3	4	5	6	7	8
Itching									
Erythema									
Oedema									
Vesicles									
Pustules									
Oozing									
Scaling									
Lichenification									
Ulcer									
Pain and burning sensation									
Varicose vein									
Family H/O of EAHU									
Others									
Signature of AL/MO									

ASSESSMENT

Eczema Area and Severity Index(EASI)Score	Before treatment	After treatment

CALCULATION OF EASI SCORE

EASI=0.1{Eh+Ih/Oh/Ph+Exh+Lh}(A)h+0.2{Eu+Iu/Ou/Pu+Exu+Lu}Au+0.3{Et+It/Ot/Pt+Ext+Lt}At+0.4{El+Il/Ol/Pl+Exl+Ll}Al

Eh-Erythema of head

Ih-Induration of head

Oh-Oedema of head

Ph-Papulation of head

Exh-Excoriation of head

Lh-Lichenification of head

(A)h-Area of head

Upper extremities-u

Trunk-t

Lower extremities-l

E, I, O, P, Ex, and L are assessed according to a 3-point scale where 0=no symptoms, 1=slight,
2=moderate, 3=marked. *A* is assigned a numerical value based on the extent of lesions in a given anatomic site: 1=<10%, 2=10-29%, 3=30-49%, 4=50-69%, 5=70-89% and 6=90-100%.

EASI SCORE=

LABORATORY INVESTIGATIONS

		Before treatment	After treatment
Blood	TC		
	DC		
	ESR		
	Hb		
	Blood sugar		
	IgE		
Urine	Albumin		
	Sugar		
	Deposit		
Specific patch test			

SIDDHA SYSTEM OF EXAMINATION

ENVAGAI THERVUGAL

	Before treatment	After treatment
Naadi		
Sparisam		
Naa		
Niram		
Mozhi		
Vizhi		
Malam		
Moothiram		

Signature of AMO **Signature of HOD**

GOVT.SIDDHA MEDICAL COLLEGE & HOSPITAL

CHENNAI-106

M.D(S)-Branch II (GUNAPADAM)

Name of the medicine : ***Navachara chunnam***

Name of the disease : ***Soothaga katti(PCOS)***

Dose & Adjuvant : As per literature 260mg to 780mg with *Soembu kudineer (Foeniculum vulgare)*. Dose will be fixed depending upon the severity of the disease

O.P. NO :	Date :	Height :
Name :	Age/Sex :	Weight :
Address :		BP :
Occupation :	Marital status :	PR :

SIGNS & SYMPTOMS	WEEKS								
	0	2	4	6	8	10	12	14	16
Irregular mensturation									
Amenorrhoea									
Oligomenorrhoea									
Dysmenorrhoea									
Body weight gain									
BMI									
Infertility									
Miscarriage									
Constipation									
Acanthosis nigricans									
Hirsutism									
Waist hip ratio									
Others									
Signature of AL/MO									

ASSESSMENT

Clinical features	Before treatment	After treatment			
		Cycle-1	Cycle-2	Cycle-3	Cycle-4
Regularity of the cycle					
Length of the cycle					
Duration of mensturation					
Level of blood flow					

LABORATORY INVESTIGATION

		Before treatment	After treatment
Blood	DC		
	TC		
	ESR		
	Hb		
	Blood sugar		
	Lipid profile		
Urine	Albumin		
	Sugar		
	Deposit		
Hormonal assay	Thyroid profile		
	LH		
	FSH		
	Estradiol		
	Progesterone		
	Testosterone		
	Insulin-fasting		
	Insulin-post prandial		
USG-pelvis Follicular study			

SIDDHA SYSTEM OF EXAMINATION

ENVAGAI THERVUGAL

	Before treatment	After treatment
Naadi		
Sparisam		
Naa		
Niram		
Mozhi		
Vizhi		
Malam		
Moothiram		

Signature of AMO **Signature of HOD**

GOVERNMENT SIDDHA MEDICAL COLLEGE AND HOSPITAL.

CHENNAI- 600 106.

M.D (siddha) - BRANCH- II. GUNAPADAM
CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms readily understood by the patient and handed over a copy of the patient information sheet.

Date: Signature of the Investigator

Name:

CONSENT BY PATIENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial and the nature of drug treatment and follow-up, including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am also aware of my right to opt out of the trial at any time during the course of trial without having to give the reasons for doing so. I, exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial of traditional remedy, namely ***Aivaeli samoola chooranam*** for the treatment of ***Karappan*** (**ECZEMA).** I understand that I may be treated with this drug for the disease.

Signature of the attending Physician

Name and Signature of the Patient

Place :

Name and Signature of witness

Date :

Relationship to patient:

GOVERNMENT SIDDHA MEDICAL COLLEGE AND HOSPITAL.

CHENNAI- 600 106.

M.D (Siddha) - BRANCH- II. GUNAPADAM
CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms readily understood by the patient and handed over a copy of the patient information sheet.

Date: Signature of the Investigator

Name:

CONSENT BY PATIENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial and the nature of drug treatment and follow-up, including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am also aware of my right to opt out of the trial at any time during the course of trial without having to give the reasons for doing so. I, exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial of traditional remedy, namely ***Navachara chunnam*** for the treatment of ***Sudhagakatti*****(Polycystic ovarian syndrome).** I understand that I may be treated with this drug for the disease.

Signature of the attending Physician Name and Signature of the Patient

Place : Name and Signature of witness

Date : Relationship to patient:

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம்
அரும்பாக்கம், சென்னை - 600 106.
केन्द्रीय सिद्ध अनुसंधान संस्थान,
अरुम्बाक्कम, चेन्नै – 600 106.
SIDDHA CENTRAL RESEARCH INSTITUTE
Arignar Anna Govt. Hospital of Indian Medicine Campus
ARUMBAKKAM, CHENNAI-600 106
(Central Council for Research in Ayurveda and Siddha, New Delhi-110 058
Under Ministry of Health & Family Welfare, Govt. of India)

Ph.Off: **044 2621 49 25**
Tele Fax: **044 26214809**
E.mail crisiddha @ gmail.com
Grams: "AYUSH" CHENNAI

19th July 2012

CERTIFICATE

Certified that the plant submitted for identification by Dr.D.Leelavathi III year P.G. (Gunapadam), Govt.Siddha Medical,College, Chennai 106, is identified as ***Diplocyclos palmatus*** (L.) C.Jeffrey Syn. ***Bryonopsis laciniosa*** (L.) Naud (Fam.Cucurbitaceae).

Sasikala Ethirajulu
Asst. Director (Pharmacognosy)

S. Jega Jothi Pandian
Asst.Director Incharge

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், அரும்பாக்கம், சென்னை - 600 106
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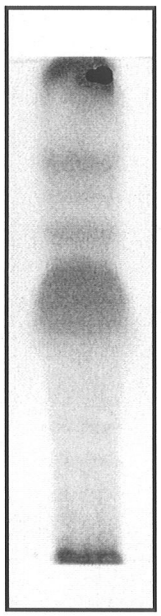
Web: www.cnsiddha.tn.nic.in

31.12.2012

Name of the student: Dr. D. Leelavathi, Govt Siddha Medical College, Chennai-106

REPORT OF AIVAELI SAMOOLA CHOORANAM

S.No	Parameter	Mean Value
1.	Loss on Drying at 105°C	8.573 %
2.	Total Ash	12.572 %
3.	Acid insoluble Ash	1.075 %
4.	Water Soluble Extractive	26.0 %
5.	Alcohol Soluble Extractive	14.85 %
6.	Particle size	Completely passes through sieve no.44
7.	pH	6.2
Qualitative Phytochemical Tests		
1.	Alkaloids	+ ve
2.	Triterpenes	+ ve
3.	Flavonoids	+ ve
4.	Saponin	+ ve
5.	Steroids	+ ve
6.	Protein	+ ve
7.	Anthraquinones	- ve
8.	Acid	- ve
9.	Coumarin	- ve
TLC		As Below



After spray with visualizing agent

Sl.No	After Dipping in Vanillin-Sulphuric acid	
	Rf value	Colour of the spot
1	0.19	Bluish grey
2	0.27	Bluish grey
3	0.53	Violet
4	0.66	Violet
5	0.73	Greenish yellow
6	0.81	Greyish blue
7	0.97	Violet

Solvent system:

Toluene : Ethyl acetate (6:1.5).

TLC plate:

Aluminium plate precoated with silica gel $60F_{254}$ of 0.2 mm thickness (Merck).

Developing chamber:

Camag's twin trough chamber.

Visualizing reagent:

Vanillin-sulphuric acid reagent.

Extract Preparation:

4 g of the chooranam was soaked overnight in chloroform. Boiled on a water bath for 10 mins, filtered and concentrated to 10 ml.

Procedure:

The extract was applied on the TLC using capillary and developed in the solvent system. The developed TLC plate was air dried and photograph was taken in white light. Then dipped in vanillin-sulphuric acid reagent, heated in an oven at 105°C until the development of coloured spots and photograph taken.

REPORT OF NAVACHARA CHUNNAM

S.No	Parameter	Mean Value
1.	Loss on Drying at 105°C	NIL
2.	Total Ash	82.036 %
3.	Acid insoluble Ash	0.577 %
4.	Particle size	Completely passes through sieve no.44
5.	pH	13.5

(R.Shakila)
Research Officer (Chemistry)

(S. Jega Jothi Pandian)
Research Officer (Scientist 2) I/c

The Tamil Nadu Dr. M.G.R. Medical University

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to Dr. D. LEELAVATHI

for participating as a ~~Resource Person~~ / Delegate in the V Workshop on

"Research Methodology & Biostatistics"

for AYUSH Post-Graduates & Researchers

organized by the Department of Siddha,

The Tamil Nadu Dr. M.G.R. Medical University

from 8th August 2011 to 12th August 2011.

Dr. MAYILVAHANAN NATARAJAN
M.S.Orth. M.Ch.Orth. (L'pool) Ph.D. D.Sc. F.R.C.S. D.Sc. (Hon)^3
VICE CHANCELLOR

Dr. SUDHA SESHAYYAN, M.S.
REGISTRAR (FAC)

Dr. N. KABILAN, M.D. (Siddha)
HOD, DEPT. OF SIDDHA

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to Dr/~~Mr/Mrs~~ D. LEELAVATHI B.S.M.S

for participating in the Workshop on

'Introduction to Scientific & Medical Writing'

organized by the Department of Epidemiology,
The Tamil Nadu Dr. M.G.R. Medical University on 18th March, 2011.

This educational activity has been awarded **10 Credit Points**
by the Centre for Accreditation, The Tamilnadu Dr. M.G.R. Medical University.

Dr. N. KABILAN, M.D. (Siddha)
HOD i/c, DEPT. OF EPIDEMIOLOGY

Dr. SUDHA SESHAYYAN, M.S.
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Dr. MAYIL VAHANAN NATARAJAN
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VICE CHANCELLOR

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

69, Anna Salai, Guindy, Chennai - 600 032.

DEPARTMENT OF SIDDHA

CERTIFICATE OF PARTICIPATION

This is to certify that Dr/Mr/Ms D. Leelavathi *has participated in the CME on* Pharmacological and Toxicological Studies *conducted by Department of Siddha on* 29-11-2010.

This educational activity has been awarded 2 *Credit points by The Centre for Accreditation, The Tamil Nadu Dr. MGR Medical University.*

Total Credits Claimed :

Participant's Signature Date

Dr. N. KABILAN
Prof & Head
Department of Siddha

Dr. SUDHA SESHAYYAN
Registrar i/c

Dr. MAYIL VAHANAN NATARAJAN
Vice Chancellor

VEL'S COLLEGE OF PHARMACY

Approved by the Government of Tamil Nadu
Affiliated to The Tamil Nadu Dr. MGR Medical University

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S.No	Title of The Project	Name of The Investigator	Approval status/Remarks	Project Reference
56.	Antiinflammatory and antihistaminic activity of Aieveli samoola chooranam	Dr. Leelavathi	Total number of animals sanctioned was 35 rats and 1guinea pigs. Permitted to proceed. But it is advised to share the common group data with similar pattern of projects if possible.	XIII/VELS/PCOL/ 56/2000/CPCSEA/I AEC/08.08.12
57.	Ovulation induction activity of siddha formulation- Navachara Chunnam	Dr. Leelavathi	Total number of animals proposed was 36 rats but 30rats were sanctioned.	XIII/VELS/PCOL/ 57/2000/CPCSEA/I AEC/08.08.12
58.	Insulinomimetic Impact Of Tannins Isolated From Indian Medicinal Plants On Glucose Oxidation And Molecular Mechanism Of Glucose Uptake On STZ Induced Diabetic Wistar Rats	Miss. S. Nirmala	Totally 48rats were proposed and sanctioned. Altered method was suggested. it was advised to share the control and standard group results	XIII/VELS/PCOL/ 58/2000/CPCSEA/I AEC/08.08.12
59.	Antipsoriatic Activity Of Herbal Formulation In Indian System Of Medicine	Miss. S. Nirmala	Total number of animals proposed was 36 mice and 18 rats but 24 mice and 12rats were sanctioned.	XIII/VELS/PCOL/ 59/2000/CPCSEA/I AEC/08.08.12
60.	Evaluation Of Anti Rheumatoid Arthritis Activity Of Pterocarpus Masupium Plant	Mrs. A.Vijalakshmi	45rats were proposed and Sanctioned	XIII/VELS/PCOL/ 60/2000/CPCSEA/I AEC/08.08.12
61.	Hypotriglyceridemic & Hypochlostrolemic Effects Of Withania Coagulans Bud Extract In STZ Induced Diabetic Rats	Dr. V.Ravichandran	Total number of animals proposed were 56 rats and as per the members suggestion data will be shared. So, totally 48animals were sanctioned.	XIII/VELS/PCOL/ 61/2000/CPCSEA/I AEC/08.08.12

Dr. J.ANBU, M.Pharm., Ph.D., D.M.L.T.,MBA.
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